

PA'INA HAWAII, LLC
Docket No. 030-36974, Mail Control No. 470601
Application for an underwater irradiator license

Background and overall summary

The U.S. Nuclear Regulatory Commission (NRC) received on June 27, 2005, from Pa'ina Hawaii, LLC, an application for the possession and use of byproduct material to be used in a commercial pool type industrial irradiator to be constructed in Honolulu, Hawaii, near the Honolulu International Airport. The proposed irradiator would primarily be used for phytosanitary treatment of fresh fruit and vegetables bound for the mainland from the Hawaiian Islands and similar products being imported to the Hawaiian Islands as well as irradiation of cosmetics and pharmaceutical products. The irradiator will also be used by the applicant to conduct research and development projects, and irradiate a wide range of other materials as specifically approved by the NRC on a case-by-case basis.

NRC held a public meeting on August 31, 2005, in Honolulu, Hawaii, to discuss the license and inspection processes that NRC staff will follow during the application review process, and to receive comments from external stakeholders on any concerns and issues associated with this license application. Earthjustice (petitioner), on behalf Concerned Citizens of Honolulu, submitted to the NRC on October 3, 2005, a request for a 10 CFR Part 2 hearing citing safety and environmental concerns. NRC's Atomic Safety and Licensing Board (ASLB) granted on January 24, 2006, the petitioner's request for a 10 CFR Part 2 hearing to determine admissibility of the petitioner's contentions.

Typically, the licensing of irradiators is categorically excluded from an environmental review as described in the NRC regulations at 10 CFR 51.22(c)(14)(vii). However, the NRC staff entered into a settlement agreement with Concerned Citizens of Honolulu, the interveners in the adjudicatory hearing on the license application. The settlement agreement included a provision for the NRC staff to prepare a draft environmental assessment (EA) and hold a public comment meeting in Honolulu, Hawaii, prior to publishing the final EA.

In accordance with the March 20, 2006, settlement agreement with Concerned Citizens of Honolulu, the NRC staff published in the Federal Register on December 28, 2006, a draft EA and draft Finding of No Significant Impact (FONSI), (71 Fed. Reg. 78231). The Federal Register notice invited public comment on the draft EA and draft FONSI and announced the staff's plan to hold a public meeting on February 1, 2007, in Honolulu, Hawaii to present the findings in the draft EA and accept comments from members of the public. More than 100 members of the public attended the February 1 meeting in Honolulu, where the staff made a 30 minute presentation on the draft EA and two hours were devoted to receiving questions and comments from members of the public. The staff issued a supplemental appendix to the draft EA (72 FR 31866) on June 8, 2007, which presented the staff's consideration of potential terrorist attacks at the proposed facility. On August 17, 2007, the staff issued its final EA and FONSI (72 FR 46249).

Safety review of the license application

The NRC has completed its evaluation of the proposed irradiator. Review of the application focused primarily on the safety, physical security, and emergency preparedness aspects of byproduct material used in the irradiator. Additionally, the technical review focused on the design of the irradiator and complementing radiation safety program as they apply to the safety of employees, the public, and the environment. 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 that may be used for human consumption after being safely irradiated. In addition to satisfying NRC regulations, Pa'ina Hawaii, LLC, must also comply with all applicable Federal, State of Hawaii, and municipal regulations.

The following description summarizes the NRC's review of the major safety topics required to be addressed in the application and applicant's commitments. Appendix C of NUREG-1556, Volume 6, was used as part of the licensing review process.

1. Radioactive material

Modern sealed sources are manufactured with double encapsulation and using nondispersible, insoluble and corrosion resistant material. These sealed sources must undergo stringent temperature, pressure, impact, vibration, puncture, and bend tests and be found leak free according to 10 CFR 36.21, Performance Criteria of Sealed Sources. The application states that Pa'ina will use Reviss Services, Inc., Model RSL-2089 and MDS Nordion, Model C-188, sealed sources. These sealed sources have been tested in accordance with the requirements of the International Organization of Standardization, ISO-2919:1999 (tests equivalent to the American National Standards Institute/Health Physics Society N43.6-1997). Irradiator sealed sources must have a minimum classification of E53424 to meet the requirements of 10 CFR 36.21 and ISO-2919. Models RSL-2089 and C-188 sealed sources were tested and successfully passed more stringent tests and received the classification E64646 and E65646, respectively. These classifications exceed the requirements specified in 10 CFR 36.21 and ISO-2919.

Models RSL-2089 and C-188 sealed sources, to be used in the Pa'ina irradiator, have undergone an engineering evaluation and have been assigned a Sealed Source and Device Registration (SSDR) certificate number IL-1082-S-101-S and NR-0220-S-103-S, respectively. Issuance of an SSDR certificate means that the sealed sources have been recognized as successfully passing different engineering tests and are suitable for being licensed in an irradiator.

Licensees are required to report leaking sealed sources to NRC and these events are recorded in the Nuclear Materials Event Database (NMED). According to a search done in NMED from 1989 to 2007 there were no reported leaking sources involving Reviss Services, Inc., Model RSL-2089 or MDS Nordion, Model C-188 sealed sources. In addition, NRC licensees are required to perform leak tests capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on a test sample or have a continuous on-line monitoring water purification system. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination,

licensees are required to file a report with the NRC within 5 days, followed by a 30 day written report, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with NRC's regulations.

2. Financial assurance

Pa'ina Hawaii, LLC, will be required to set aside, under NRC control, monetary funds destined for decommissioning financial assurance. The applicant committed to provide the required financial assurance of \$113,000, as per 10 CFR 30.35(d), before acquiring the sealed sources.

3. Purpose for which licensed material will be used

Use of proposed licensed material is consistent with the description provided in the Sealed Source and Device Registration certificates number IL-1082-S-101-S and NR-0220-S-103-S for use in a Gray*Star Model Genesis II irradiator for the irradiation of material except explosives, and flammable or corrosive material.

4. Individuals responsible for radiation safety program

Applicant will have in place a Radiation Safety Committee. The proposed Radiation Safety Officer (RSO) has adequate training and experience and received specific vendor training for RSO duties associated with a Gray*Star Model Genesis II irradiator. Additional manufacturer's training will be provided to the RSO during pre-operational testing (simulator mode with no sources). The RSO will have full authorization to stop unsafe practices and has direct line of communication with the president of the company. The proposed operator will receive manufacturer's training in the operation of the irradiator (simulator mode with no sources) prior to becoming a qualified operator.

5. Individuals working in or frequenting restricted areas

NRC regulations require access controls for workers, visitors, and the public to ensure that radiation doses to these groups are within the limits prescribed by regulation and are as low as reasonably achievable. These controls consist of specialized training, radiation monitoring, personnel monitoring, audit programs, access barriers, and other engineering controls that may reduce radiation doses. The applicant committed to enforce access control on restricted areas and provide escort to non trained individuals.

6. Facilities and equipment

NRC's Region IV engineering staff with expertise in the areas of geotechnical, concrete, and construction reviewed the applicant's geotechnical report and responses received from requests for additional information. A summary of the overall assessment follows.

- Radiation monitors - Irradiator will have a water radiation monitor which will operate in a continuous mode and an area radiation monitor mounted over the pool.
- Irradiator manufacturing facility - Staff performed a site visit of the manufacturing facility, CHL Systems, in August 2006, to review pool drawings, welding procedures, and manufacturing processes.
- Pool Integrity - The applicant meets the requirement of 10 CFR 36.41(c) for testing the pool integrity based on staff assessment of applicant's responses.
- Overhead Hoist - The overhead trolley, rail and hoist that is used to move material over the pool is not regulated by 10 CFR 36. However, adherence by the applicant to industry standard ANSI B30.16, "Overhead Hoists (Underhung), and the use of a good rigging program should provide adequate protection against catastrophic failure of the trolley, rail or hoist.
- Pool Design - The pool will be designed and fabricated to resist a combined at-rest fluid and hydrostatic pressure substantially greater than the minimum recommend value. Corrosion of the carbon steel pool components are expected to be minimal and are not anticipated to degrade the stainless steel pool liner.
- Concrete Pool Foundation - The applicant's proposed process for placing the concrete foundation beneath the pool under different scenarios appear to be adequate based on staff assessment of applicant's responses.
- Potential Soil Liquefaction -Staff calculations using equations found in engineering literature and Regulatory Guide 1.198 indicated that the factor of safety against liquefaction would be in an acceptable range as long as the Standard Penetration Test (SPT) blowcount from the soil boring was of an adequate value. Actions that the applicant will take to avoid soil liquefaction appear to be adequate based on staff assessment of applicant's responses.
- Seismic Separation - A horizontal separation of six inches between the sides of the irradiator pool and the building slab should provide adequate isolation during a seismic event typical of the area.
- Pool Excavation Depth - Actions that the applicant will take to determine the pool excavation depth appears to be adequate based on staff assessment of applicant's responses.

- Concrete Placement - Adherence to standard industrial construction practices by the applicant should be sufficient to prevent voids during concrete placement activities.
- Proposed Construction Techniques - Proposed construction techniques for different scenarios appear to be adequate based on staff assessment of applicant's responses.
- Inspections activities recommended during the construction phase:
 - Inspection of the pool fabrication activities to show that the pool is leak resistant and meets design specifications as required by 10 CFR Part 36 for pool irradiators.
 - Inspection of pool excavation activities to verify that the soil layer is adequate to support the pool foundation.
 - Inspection of the concrete placement activities for the pool foundation and pool installation. Inspection activities should include observing the concrete mix, the actual placement, concrete consolidation techniques, and review of concrete test results.
 - Review of the pool liner and the leak test documentation performed at the fabrication facility. Observation of final leak test of the pool liner after the pool has been placed on the foundation.

NRC plans to have inspection presence during key portions of the pool construction phase, loading of sealed sources and pre-operational testing of the irradiator.

7. Radiation Safety Program

- The applicant will have adequate survey meter instrumentation and instruments will be calibrated annually.
- Area radiation monitor and water radiation monitor will be programmed to alarm at readings over 1 milliRoentgen an hour.
- Occupational dosimetry and public dose assessment will be verified during NRC inspections.
- The licensee will not perform repairs or alterations of the irradiator (non-routine operations) involving removal of shielding or access to the licensed material. Installation, removal, replacement, and disposal of sealed sources in the irradiator will be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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- Operating and emergency procedures are outlined and described in the application. Adherence to operating procedures for source loading, unloading, and repositioning (Safeguards Information - Modified Handling), will be reviewed during inspection.
- Applicant will comply with 10 CFR 36.59 by means of a continuous water radiation monitor.
- Inspection and maintenance checks were submitted with the application.
- Transportation - The applicant will not be transporting licensed material. Licensed material required for irradiators will be transported by the sealed source manufacturer in lead-shielded steel transportation casks. These transport casks meet national and international standards modeled upon the Regulations for Safe Transport of Radioactive Materials of the International Atomic Energy Agency (IAEA). Additionally, these casks are designed to withstand the most severe accidents, including collisions, punctures, and exposure to fire and water depths. Transportation aspects will be reviewed during inspection.
- Waste management - The applicant will make contractual arrangements with the sealed source manufacturer to return unused sources.

8. Additional security measures

In response to the terrorist attacks of September 11, 2001, the NRC, issued Orders, to large panoramic and underwater irradiator licensees, requiring them to implement additional measures for enhanced security. These additional measures include access controls for workers, visitors and the public. The applicant will need to comply with fingerprinting and irradiator orders. These orders will be issued before the applicant acquires the sealed sources.

Based on the information described above, the NRC staff has determined that the application satisfies all NRC's requirements in 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators." Based on the results of NRC's safety and security review, the staff concludes that a license can be issued to Pa'ina Hawaii, LLC, for the possession and use of licensed material in an irradiator.

NRC will conduct frequent unannounced inspections to assure compliance with the terms and conditions of the license and NRC regulations.

Date: August 17, 2007

/RA/

License reviewer:

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