CURRENT REGULATORY AND LICENSING STATUS

FOR BYPRODUCTS SOURCES, FACILITIES, AND APPLICATIONS

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ABSTRACT

Public use of nuclear byproducts, especially radioactive isotopes, will require approval by various regulatory agencies. Use of cesium-137 as an irradiation source for sterilizing medical products will require U.S. Nuclear Regulatory Commission (NRC) approval. Two applications have been filed with NRC, and approval is expected soon. Widespread use of irradiation for food products depends on a favorable ruling by the Food and Drug Administration (FDA). A ruling is pending that would permit irradiation of fruits and vegetables up to 100 krad. NRC also controls the use of isotopes in remote power generators, but little regulatory action has been required in recent years. Recent development of radioluminescent (RL) lighting for runway lights has led to interest by commercial manufacturers. At the present time, a license has been issued to at least one manufacturer for sale of tritium-powered runway lights.

INTRODUCTION

Of the very large number of fission products produced in nuclear reactors, only a few have been seriously considered for wide-scale application. Most of these applications take advantage of the radioactivity of the isotope, although there are notable exceptions such as xenon, some applications of krypton, and the noble metal fission products (palladium, rhodium, and ruthenium). Since nuclear byproducts are either radioactive themselves or may be contaminated with radioactivity, their application on a broad scale requires approval by regulatory agencies. In this paper, regulations regarding the uses of byproduct cesium-137 irradiation sources, strontium-90-fueled remote power generators, and tritium-powered RL lighting are discussed.

CESIUM-137 IRRADIATION SOURCES

Application of irradiation sources requires approval by two separate regulatory agencies: the NRC and the FDA. The NRC has stated that their concern is only with basic licensing and radiation safety of the workers and the general public. They do not address the quality of the products subjected to irradiation except to assure that they remain free of radioactive contamination. [1] The FDA's main concern is the safety and usefulness of the irradiated product. The present status of regulations regarding the use of irradiation sources in the United States is presented in the following paragraphs.

Regulation by the Food and Drug Administration

The FDA controls the use of cesium-137 irradiation sources for any product that may be used for human consumption or be in the food chain of man. Although there are many present and potential uses of irradiation sources, the FDA concerns themselves mainly with irradiation of disposable medical products and items in the food chain.

Irradiation Sterilization of Medical Devices

Sterilization of medical products by ionizing radiation is one of five satisfactory methods recognized in the United States Pharmacopeia (USP); the others are steam, dry heat, ultrafine filtration, and gas sterilization. Ionizing radiation sources given in the USP are electron accelerators and radioisotope sources such as cobalt-60 and cesium-137. [2]

The irradiator operator has the burden of proof for product sterility. Consequently, well-trained personnel and their continuous surveillance of equipment and procedures are required.

The FDA has seen no safety problems with irradiation sterilization of medical devices. However, periodic monitoring of records and facilities is required to assure that irradiators perform the function claimed and comply with the good manufacturing practices for medical devices described in 21 CFR 820. The FDA may also perform USP sterility tests.

Food Preservation by Irradiation

Man's continuing need for palatable food has led to parallel innovations in both food preservation and laws that attempt to ensure the wholesomeness of food. Irradiation is the most recent preservation process to be developed. The following paragraphs briefly describe the actions that have led us to the point where irradiation is nearing acceptance for treatment of food. A chronology of some of these developments is shown in Fig. 1.

Although many improvements have been made in preservation methods, no major new techniques were conceived until the 1930s when a French patent was issued for food irradiation. The earliest series of experiments for food sterilization by irradiation were conducted in 1943 on hamburger by Dr. D. E. Proctor of the Massachusetts Institute of Technology (MIT) under a contract with the U.S. Army Quartermaster Corps. In March 1953, Dr. R.G.H. Siu, the Associate Technical Director of the Quartermaster Corps, undertook a feasibility study on the development of radiation preservation for a broad spectrum of foods. His report called for a five-year R&D program under the Corps' leadership, which led to a national program.

Fig. 1. Food Preservation and Regulation - Milestones and Interactions.

Perhaps the greatest force toward fully supporting both U.S. and worldwide food irradiation research was President Eisenhower's plea for "Atoms for Peace" before the United Nation's General Assembly on December 8, 1953. He proposed a "way by which the miraculous inventions of man shall not be dedicated to his death, but consecrated to his life," and he advocated the creation of the International Atomic Energy Agency (IAEA). The IAEA, the World Health Organization (WHO), and the Food and Agriculture Organization (FAO) are U.N. bodies that have long fostered development of irradiation for food preservation. [3]

Since one goal of food irradiation programs, such as those conducted by the U.S. Army and later by the Atomic Energy Commission (AEC), was to preserve food for general consumption, it was inevitable that the FDA would become involved due to its mandate for food quality protection. Early on, Army scientists informed the FDA of its activities and consulted with the FDA with respect to the design of long-term animal feeding protocols and other means for evaluating safety factors. [4]

Federal orders delegate that the FDA administer several laws that ensure the wholesomeness of foods consumed by the U.S. public. The principal law implemented by the FDA was the Food, Drug, and Cosmetics Act of 1938, including the Food Additives Amendment of 1958 and the Pesticide Chemical Amendment of 1954. Both of the amendments have affected the use of food irradiation. The first considers radiation as an additive when it is used to treat foods; thus, it controls what foods may be irradiated and to what extent. The second considers pesticide residues on foods; thus, it keeps potentially harmful residues to a minimum or, as in the case of residues of ethylene dibromide (EDB), prevents their accumulation by banning use of the additive. It is the elimination or severe restriction of the use of certain pesticides that has recently rekindled an interest in food irradiation, for which there was a lull from about 1970 to 1979.

In the United States, the first law regulating food quality was passed in 1784 by the State of Massachusetts; in 1850, this state established its Pure Food and Drink Law. The first general food law for the United States came into effect on June 30, 1906, when the Food and Drug Act was passed by Congress and signed by President Theodore Roosevelt. The act prohibited the manufacture of adulterated or misbranded foods or drugs in the United States and required that foods be prepared in a sanitary manner from pure and wholesome materials and be free of any additives that would be injurious to health. In 1927, the FDA was formed within the U.S. Department of Agriculture and assumed the enforcement role.

In 1938, the original 1906 act was completely revised as the Food, Drug, and Cosmetics Act. It barred any adulterated, misbranded, or harmful food, drug, or cosmetic from interstate commerce. Labeling requirements were made more specific to provide more

information to the consumer. This was essentially the way the law stood when the Army requested the FDA's advice in 1953 on the nutritional and toxicological aspects of irradiated foods. [5] FDA's cooperation was the first interaction of the development of food irradiation technology and application of the law.

On September 6, 1958, the U.S. Congress passed the Food Additives Amendment of 1958. This act amended the Food, Drug, and Cosmetics Act to protect the public health by prohibiting the use of additives in food that have not been adequately tested to establish their safety. [6] The term "food additive" was defined in the amendment as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, . . . processing . . . , treating, packaging . . .; and including any source of radiation intended for such use). . . ." Radiation is included in the additives amendment as an adulterant additive if a food "has been intentionally subjected to radiation."

The key portion of the amendment that has severely limited the use of irradiation is the Delaney clause: "No such [additive] regulation shall issue if a fair evaluation of the data . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation will be safe: Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; . . . or would promote deception. . . ." Because of this amendment, the FDA must determine that the proposed use of a food additive (including radiation) is safe and that it will accomplish the intended use before a regulation authorizing such use can be established. [7]

Irradiation of Food Petition and Regulations

The first FDA regulation relating to food radiation was issued in July 1960. This regulation was for the use of radiation devices in controlling or checking fill levels of containers or storage tanks and the density of syrups of canned fruits.

By 1962, the Army food irradiation testing was becoming productive; and a petition was filed on August 17 to allow irradiation of canned bacon. [8] The safety data supporting the petition claimed that 1) there was no consistent difference in radioactivity between irradiated bacon and the canned control; 2) there was no increase of tumors in mice or beagles; 3) wholesomeness was established based on tests with rats, beagles, and humans; 4) a dose of 4.5 Mrad provides a safe process for canned bacon even under gross contamination with Clostridium botulinum.

These results were typical of a series of petitions for irradiating foods submitted to the FDA between 1962 and 1967. During this period, petitions were filed for wheat and wheat products, white potatoes, citrus fruits, strawberries, ham, marine products, and various packaging materials.

The FDA issued its canned bacon regulation on February 8, 1963, followed by regulations for wheat and wheat products, white potatoes, and a number of packaging materials. In 1966, the AEC submitted a petition for approval of irradiation of strawberries. Since the FDA had allowed data from testing of one food to apply to approval of another, the strawberry petition included long-term feeding data from Army tests of canned peaches. The FDA's interpretation of the peach testing data was that rodents fed irradiated canned peaches in the two-year feeding studies exhibited an apparently higher incidence of tumors than those fed nonirradiated peaches. The data thus suggested an adverse effect of irradiation in peaches; the FDA stated that this was not proof of hazard, but rather, no proof of safety. Furthermore, they refused to allow the testing of similar foods to apply to the strawberry petition. Because of the rejection of data from peach testing, two-year animal feeding tests would have been required to establish the safety of irradiated strawberries; consequently, the AEC withdrew its petition. [9] About the same time, the Army withdrew its petition for irradiation of canned peaches.

About this time, the petition for high-dose radiation processing of ham was under evaluation. Alerted by the apparent adverse effects from the review of the peach irradiation study, the FDA requested that all the raw data from ham testing be supplied for its own evaluation. From its subsequent study, the FDA interpreted that these data also showed possible adverse effects on animals fed irradiated ham. The FDA informed the Army that favorable action on the ham petition could not be recommended in the absence of proof of safety of irradiated ham. [9]

The results led to the FDA's calling for a complete reexamination of all the raw data on which the canned bacon regulations were based. In its earlier evaluation to establish the bacon regulation, the FDA had relied on the Army's summary evaluation on animal feeding tests. In the FDA's view, the raw data for testing animals fed irradiated bacon showed that there were significant adverse effects that were not due to chance. These effects included animal reproduction, increased mortality in rats, slight depression in rate of weight gain in mice and dogs, reduced blood cell counts in dogs and rats, and a higher incidence of cataracts and tumors in animals. The FDA concluded, in contradiction to the viewpoint of the Army, that the safety of irradiated bacon had not been demonstrated and revoked the canned bacon regulation on August 15, 1968. [9]

As a result of the FDA's refusal to approve the ham petition and its withdrawal of the bacon regulation, the food programs of the Army, the AEC, and commercial firms were delayed at least the four- to five-year period required to conduct new animal tests. [10] By 1970, because of escalating FDA requirements and fiscal restraints, the AEC activity was limited to its support of the International Food Irradiation Project (IFIP). The Army continued to develop food irradiation technology and to study irradiation sterilization of meats and poultry. [3,11]

Even though U.S. interest and activities had subsided, worldwide activities continued. In 1966, 33 countries were participating in international research programs; by 1972, the number had grown to 55. [12] Based on its findings from food irradiation projects, the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food (JECFI) recommended unconditional acceptance in 1966 of five irradiated foods (chicken, papaya, *potatoes*, *strawberries*, and wheat) and proposed provisional acceptance of four others.

Perhaps more importantly, the JECFI declared its departure from the food additive concept by stating that irradiation is a physical process for treating foods and as such it is comparable to heating or freezing foods for preservation. The Committee stressed that the microbiological, nutritional, and toxicological approaches to the assessment of the wholesomeness of irradiated food must be based on the concept of food irradiation as a process. The JECFI report further noted that analyses of radiolytic products removed the uncertainties of extrapolating from one food to another, and the general principle of radiation-induced chemical reactions would reduce the amount and simplify the toxicological testing needed. [13] In November 1980, the JECFI recommended the acceptability of any food commodity irradiated up to an overall dose of 10 kGy (1 Mrad). Toxicological testing of foods to this dose should not be required. [14] In July 1983, the FAO/WHO Codex Alimentarius Commission[a] approved the recommendation and adopted the Codex General Standard for Irradiated Foods, which allows foods to be processed by ionizing radiation up to an overall dose of 10 kGy (1 Mrad).

In about 1979, the U.S. interest in irradiation was rekindled because it was thought that food irradiation could be an alternative for toxic fumigants, such as EDB, for disinfesting fruits and spices. In late 1979, the Bureau of Foods Irradiated Food Committee (BFIFC) was established. This committee recommended criteria for safety evaluation according to the current state-of-the-art knowledge in toxicology, nutrition, and radiation chemistry. The BFIFC also recommended that foods irradiated at doses up to 100 krad be considered wholesome and safe for human consumption. [5,15]

Because of the lack of knowledge about the amounts of radiolytic products formed in food by the irradiation process, an entire food was treated as an additive in the earlier testing. Frequently, it was not possible to feed test animals the exaggerated amounts of food required to obtain a 100-fold safety factor for human consumption without causing the animals dietary stress or nutritional imbalance. [5] It became clear to the BFIFC that assessing the toxicity of each irradiated food is impractical and unworkable and that scientists should, instead, focus on the safety of the radiolytic products to evaluate the safety of irradiated food. This latter method of evaluation was possible because scientists had become more knowledgeable about the chemistry of foods, including the identity, quantity, and toxicity of radiolytic products formed. [16]

As a consequence of the BFIFC report, the FDA issued, as a first step, an Advance Notice of Proposed Rulemaking (ANPR) in 1981 for regulating irradiated foods and solicited public comments. The actions being considered would allow irradiation of any food below 100 krad, include guidelines for preparation of petitions, and create a policy that a food class comprising only a minor portion of the daily diet, such as spices, could be irradiated at a dose of 5 Mrad or less. [15] In 1983, the FDA issued a final rule allowing irradiation of spices and vegetable seasonings up to doses of 1 Mrad to reduce or control microbial contamination. [17]

(a) The Codex Alimentarius Commission is a regulatory unit of the United Nations FAO that adopts standards for possible enactment by countries throughout the world.

On February 14, 1984, the FDA published its proposed rule, "Irradiation in the Production, Processing, and Handling of Food," in the Federal Register. The proposed rule would allow irradiation not exceeding 100 krad for growth and maturation inhibition and insect disinfestation of foods and irradiation not exceeding 3 Mrad for microbial disinfection of dried spices and vegetable seasonings. It also required that food be treated only to the minimal radiation dose reasonably required to accomplish the technical effect. A scheduled process would be mandated to ensure the adequate dose range. Labeling would be required for irradiated foods shipped between manufacturers and processors to ensure that the food would not be irradiated again.

At the National Food Processors Association convention in February 1984, M. M. Heckler, Secretary of Health and Human Services, said, "The proposed regulation caps a forty-year, $80-million effort by the federal government and the food industry to find a safer, more effective way to rid foodstuffs of harmful insects and retard spoilage." She described the amount of irradiation treatment that would be allowed for food as being conservative, almost cautious, and well within the bounds of safety for human consumption. She added that further research is needed and that if higher doses of irradiation are safe "a second proposal will be issued." [18]

As yet, the final version of the 1984 proposed rule has not been issued, but it is expected early in 1985. Issuance of the new rule will be a culmination of the long interaction between the development of food irradiation technology and implementation of food wholesomeness laws.

Status of NRC Licensing Activities

The NRC authority comes from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. These acts cover the use of byproduct material as well as other source and special nuclear materials. In addition, under the Atomic Energy Act, the NRC can enter into agreements with states, thus transferring primary regulatory authority to the state where the facility is located. The 27 agreement states regulate all privately owned or local government irradiators in their own state, but the NRC regulates those owned and operated by federal government agencies.

Radioisotopes have been used in commercial irradiators since the mid-1960s, and there are about 35 commercial irradiators licensed by the NRC and agreement states. [1] All of these irradiators use cobalt-60 as the irradiation source. From the byproduct point of view, the principal interest is the use of fission product cesium-137 for irradiation sources. In 1983, the U.S. Department of Energy (DOE) requested that NRC register the Hanford Waste Encapsulation and Storage Facility (WESF) cesium-137 capsule as a sealed source. NRC declined but agreed to evaluate the first few irradiators on a case-by-case basis. Two types of irradiators are being considered: 1) capsules loaded into the irradiator under water, stored in air with irradiator operation in air (wet load, dry storage, dry operation) and 2) capsules loaded under water, stored in a water pool with operation in air (wet load, wet storage, dry operation).

The first type of irradiator is similar to the operating mode of the DOE-owned Sandia Irradiator for Dried Sewage Solids (SIDSS) in Albuquerque, New

Mexico, which has been in operation for over six years. The second type is similar to most commercial cobalt-60 irradiators. DOE and NRC have agreed that the SIDSS irradiator will be used as a demonstration for the wet load, dry storage, dry operations systems. A capsule will be periodically removed and destructively examined to measure corrosion, weld degradation, and mechanical properties.

The first wet load, wet storage, dry operation irradiator will also be a demonstration facility. DOE will sponsor periodic destructive examinations of the capsules from this facility. In addition, the effects of corrosion and thermal cycling of the capsules will be investigated.

Qualification tests were completed by DOE contractors on the WESF capsules more than a decade ago following the tests outlined in American National Standards N542. The requirements for thermal, impact, vibration, and puncture tests were shown to be met.[19] In addition, a series of tests were completed to measure the corrosion rate of the stainless steel cladding by the salt. Earlier tests had shown little or no corrosion at temperatures up to 600°C with pure cesium chloride. However, recent tests using actual WESF capsules indicated a significant corrosion rate at 450°C that was apparently due to impurities in the salt.[20] Examination of capsules removed from SIDSS, however, showed that at normal irradiator temperatures (200°C at the salt/capsule interface) the corrosion rate is unobservable, even after nearly six years at temperature.

A thermal cycle test is nearing completion at PNL that is designed to investigate the effect of thermal stresses on the weld during the rapid cooldown that occurs when a capsule in thermal equilibrium with air is immersed in a water pool. The satisfactory completion of these tests together with the continued surveillance of capsules from the two demonstration irradiators is expected to satisfy NRC requirements.

Two requests for licensing of irradiators using WESF cesium-137 capsules are currently being evaluated by the regulatory agencies. The first facility, a wet load, dry storage, dry operation system using 12 MCi in WESF cesium capsules, is being licensed by an agreement state and is expected to receive its license in the spring of 1985. The second application is a request for an amendment to a present license for a cobalt-60 irradiator. The amendment would permit the use of WESF cesium-137 capsules in conjunction with cobalt in a wet load, wet storage, dry operation irradiator. Since this is expected to be the first use of WESF cesium in this type of irradiator, capsules will be withdrawn periodically for examination.

STRONTIUM-90 REMOTE POWER SOURCES

Fission product strontium-90, along with its daughter product yttrium-90, is primarily a beta-emitting isotope that generates 149 watts/Ci of thermal energy. This energy has been used for nearly 25 years for small remote power generators. These radioisotope thermoelectric generators (RTGs) are in many respects similar to the plutonium-238 fuel power generators used extensively in space applications. Although most RTGs have been used by the U.S. military or by foreign countries, NRC has approved their use in several cases of commercial use in the United States. In general, the manufacturer is required to obtain a certificate of compliance to transport the generator to the user's location. However, the operating license is the responsibility of the user.

Strontium-90-fueled generators using thermoelectric conversion have been manufactured with an output of up to 100 watts of power and licensed by the NRC. DOE is developing a 500-watt RTG to demonstrate the feasibility of building larger generators for a variety of applications. Efforts to meet regulatory requirements for this demonstration unit will be discussed in a later paper.

In addition, DOE has contracted for construction of a strontium-90-fueled power generator at PNL that will use a dynamic power conversion system. This generator will use a 1-kWe Stirling engine converter heated by six WESF strontium capsules. Since the generator is to be used only at DOE facilities, no licensing action has been initiated. However, licensing would require a thorough evaluation of the capsule integrity as well as the entire system for transport and use.

RADIOLUMINESCENT AIRFIELD LIGHTING

In this section, the issues affecting the use of RL lights for airfield applications are discussed. Major NRC and Federal Aviation Administration (FAA) requirements are identified, and the status of efforts to meet them is discussed.

NRC Requirements

Licensing of RL lights for use for airfield lighting and marking will be handled under the provisions of the Atomic Energy Act of 1954, subsequent legislation, and the rules of Title 10, CFR, Parts 30 through 35 (10 CFR 30-35).[21]

The NRC issues either a general or a specific license for use of byproduct materials. A specific license is issued to a named person upon application filed pursuant to the Code of Federal Regulations. The NRC also issues general licenses permitting anyone to receive, possess, use, or transfer byproduct material contained in, "devices designed and manufactured for . . . producing light," provided the devices have been manufactured and initially transferred[21,22] and shipped[23] in accordance with a specific license issued or the equivalent requirements of an agreement state. Existing regulations are directed at the use of millicurie quantities rather than the larger multicurie quantities of tritium or krypton-85 to be used in RL lights for runway lighting and marking purposes.

Since each light is expected to contain more than 30 Ci of tritium, the major burden for licensing is placed on manufacturers, who are required as a minimum to complete and meet the testing and certification requirements.[24] Specific documentation showing that the test requirements were met would be provided by the manufacturer. The least burdensome license for tritium-activated runway markers appears to be a generally licensed light unit. The total quantity of radioactive material for a runway or landing field is too great to be considered as exempt. Presently, this general licensed status has not been achieved. In the case of the RL lights and their use, the required documentation for the user having a license should be minimal. The manufacturer's general license for the light itself requires a thorough environmental evaluation and should suffice, providing the user has appropriate storage and

handling facilities for installation and replacement purposes.

At the present time, at least one manufacturer has obtained an NRC license and produced a light containing 120 Ci of tritium, which may be usable for helicopter operations. The total quantity of tritium possessed by the user for helicopter landing pads could exceed several thousand curies at any given time. Oak Ridge National Laboratory (ORNL) under contract with DOE has completed extensive testing on RL lights, demonstrating that units exceed existing requirements for runway lighting.[25] Prototype lights produced at ORNL have also been used in extensive field testing for both military and civilian use. During these tests, the lights were handled and stored in a fashion similar to that planned for commercial use. In some instances, single tubes have failed after several months use; the cause is being examined. In no case has tritium exposure been significant.

Federal Aviation Administration Approvals

The need for a self-powered, low-cost lighting system for rural Alaskan (and northern) runways has been identified.[26-28] Tritium-powered RL lights under development by DOE in cooperation with the U.S. Department of Defense and the State of Alaska Department of Transportation and Public Facilities (DOT&PF) have been demonstrated as a technology that can meet this need. Thus, the State of Alaska has requested FAA approvals for appropriate use of the technology as a safe alternative lighting system to meet the airfield lighting needs of air taxi operations and general aviation in the state.

FAA requires that lights and landing aids provide nighttime visual guidance for approach and landing operations. Specific criteria are established in the Federal Aviation Regulations for the aircraft being flown and meteorological conditions encountered.

An evaluation of the lights was performed at a rural airfield near Richland, Washington.[28] The tests and results of this work are a start to ensuring safe and reliable lighting at rural Alaskan airports and other locations. A summary of the results of this test follows.

All pilots could identify, maintain contact with, and use the runway from 1.5 miles or greater during approach; and most felt that they could have landed. In addition, pilots reported that they could use the lights for runway alignment from distances of 2 miles under very dark clear conditions and between 1.5 and 2 miles under 3/8 to 2/3 moonlight and hazy conditions. Some pilots and observers reported visual contact with the runway at 3 to 3.5 miles along the extended runway centerline and 2 to 2.5 miles when 90° from the runway direction. Other observations included:

- The use of extra edge lights may be more effective than increasing the light emission from the threshold area.
- A navigational aid, such as a strobe light, is needed to lead civilian pilots to the airfield. Once the pilot is in the vicinity of the airfield, the RL lights are a good landing aid.
- FAA flight standards pilots evaluating the lights felt that they could be used for air taxi operations.
- The lights worked well under the weather conditions of the tests, but testing did not include adverse weather conditions.
- A visual glide slope indicator was needed.
- Pilot vision and/or training may be an important factor and may account for the variation in visual contact, usable acquisition distances, and the high approach reported by several pilots.
- Improvement in the wind direction indicator was needed.

Based on these results, we anticipate limited approval to use the lights on a runway at Central, Alaska, for long-term evaluation under a variety of weather conditions. The Central site is accessible year around from Fairbanks, Alaska, and would provide a satisfactory location for the second step in gaining the appropriate FAA approvals for RL light usage.

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REFERENCES

1. Testimony of Richard E. Cunningham before Subcommittee on Energy Research and Production, Committee on Science and Technology, U.S. House of Representatives, July 26, 1984.

2. "Sterilization," The United States Pharmacopeia, XIX, pp. 709-714, United States Pharmacopeia Convention, Inc., Rockville, Maryland (1975).

3. A. BRYNJOLFSSON, "The High Dose and Low Dose Food Irradiation Programmes in the United States," IAEA Food Preservation by Irradiation, Vol. 1, pp. 15-27, International Atomic Energy Agency, Vienna (1978).

4. G. P. LARRICK, "Statement for Presentation to the Joint Committee on Atomic Energy." In Hearings Before the Joint Committee on Atomic Energy, Congress of the United States, on National Food Irradiation Research Program, U.S. Government Printing Office, Washington, D.C. (1960).

5. Testimony by Sanford A. Miller before Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, May 9, 1984.

6. Public Law 85-929, 85th Congress, H.R. 13254, September 6, 1958, Food Additives Amendment to Federal Food, Drug, and Cosmetic Act.

7. R. S. ROE, "State of FDA Responsibility," Isotopes and Radiation Technology, 3, 4, 358 (1966).

8. Hearings before the Subcommittee on Research, Development, and Radiation of the Joint Committee on Atomic Energy, 89th Congress of the U.S., June 9-10, 1965. Radiation Processing of Foods, U.S. Government Printing Office, Washington, D.C. (1965).

9. Hearings before the Subcommittee on Research, Development, and Radiation of the Joint Committee on Atomic Energy, 90th Congress of the U.S., July 18 and 30, 1968. Status of the Food Irradiation Program, U.S. Government Printing Office, Washington, D.C. (1968).

10. "The U.S. Radioisotope and Radiation Processing Industries - 1968," Isotopes and Radiation Technology, 6, 3, 235 (1969).

11. E. E. FOWLER, "Overview of USAEC Interest in Food Irradiation," in Disinfestation of Fruit by Irradiation, STI/PUB/299, International Atomic Energy Agency, Vienna (1971).

12. H. E. GORESLINE, "IAEA Round Table Discussion: Action Plan on Food Irradiation," in Food Preservation by Irradiation, Vol. 2, STI/PUB/470, International Atomic Energy Agency, Vienna (1978).

13. J. F. DIEHL, "Food Irradiation - Worldwide Activity," Food Engineering, pp. 82-84 (1978).

14. J. VAN KOOIJ, "Food Irradiation Makes Progress," IAEA Bulletin, 26, 2, 17-21 (1984).

15. Advance Notice of Proposed Rulemaking, Policy for Irradiated Foods; Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption, 21 CFR 21, FDA, Federal Register, 46, 59, 18,982, March 21, 1981.

16. Proposed Rule: Irradiation in the Production, Processing, and Handling of Food, FDA, 21 CFR Part 179, Federal Register, 49, 31, 5714, February 14, 1984.

17. Federal Register, 48, 30,613, July 5, 1983.

18. C. E. MORRIS, "FDA Proposes Irradiation for Fruits and Vegetables," Food Engineering, pp. 21-22 (1984).

19. G. L. TINGEY, E. J. WHEELWRIGHT, and J. M. LYTLE, A Review of Safety Issues tnat Pertain to the Use of WESF Cesium Chloride Capsules in an Irradiator, PNL-5170, Pacific Northwest Laboratory, Richland, Washington (1984).

20. G. H. BRYAN, Cesium Chloride Compatibility Testing Program Annual Report - Fiscal Year 1983, PNL-4847, Pacific Northwest Laboratory, Richland, Washington (1983).

21. U.S. Code of Federal Regulations, Title 10, Sections 30-35.

22. U.S. Code of Federal Regulations, Title 49, Sections 100-199.

23. U.S. Nuclear Regulatory Commission, "Guide for Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material," Regulatory Guide 10.7, Washington, D.C. (1979).

24. U.S. Department of Commerce/National Bureau of Standards, American National Standard N540 Classification of Radioactive Self-Luminous Light Sources, NBS Handbook 116, Washington, D.C. (1976).

25. Oak Ridge National Laboratory, "Tritium Radioluminescent Lighting Development," presented at Technology Transfer Conference, March 21-22, 1984, Oak Ridge, Tennessee (1984).

26. G. A. JENSEN et al., Examination of the Feasibility for Demonstration and Use of Radioluminescent Lights for Alaskan Remote Runway Lighting, PNL-5183, AK-RD-84-16, Pacific Northwest Laboratory, Richland, Washington (1984).

27. G. A. JENSEN, and L. E. LEONARD, Radioluminescent Lighting for Alaskan Runway Lighting and Marking, PNL-5328, Pacific Northwest Laboratory, Richland, Washington (1985).

28. G. A. JENSEN, Acceptability Testing of Radioluminescent Lights for Nighttime Air Taxi Landing Operations, PNL-5347, Pacific Northwest Laboratory, Richland, Washington (1985).