GRAY STAR

June 17, 2005

Jack Whitten
Reg. IV, US NRC
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064
800-952-9677

RECEIVED
JUN 20 2005
DNMS

Dear Mr. Whitten:

Enclosed is a package of information on the GRAY*STAR Genesis Irradiator™.

This is general information on the Genesis Irradiator. Please don't forget to check out our web site at: www.GrayStarInc.com

Your office will shortly be receiving an Application for a Material License from one of our customers located in Hawaii. The information that is enclosed is either information of the first installation of a Genesis unit or general information on the irradiator and its application. This information is independent from the Application that you will soon receive.

If there are any questions, please contact me.

I look forward to working with you and your staff in the near future.

Sincerely,

Russell N. Stein
Vice President

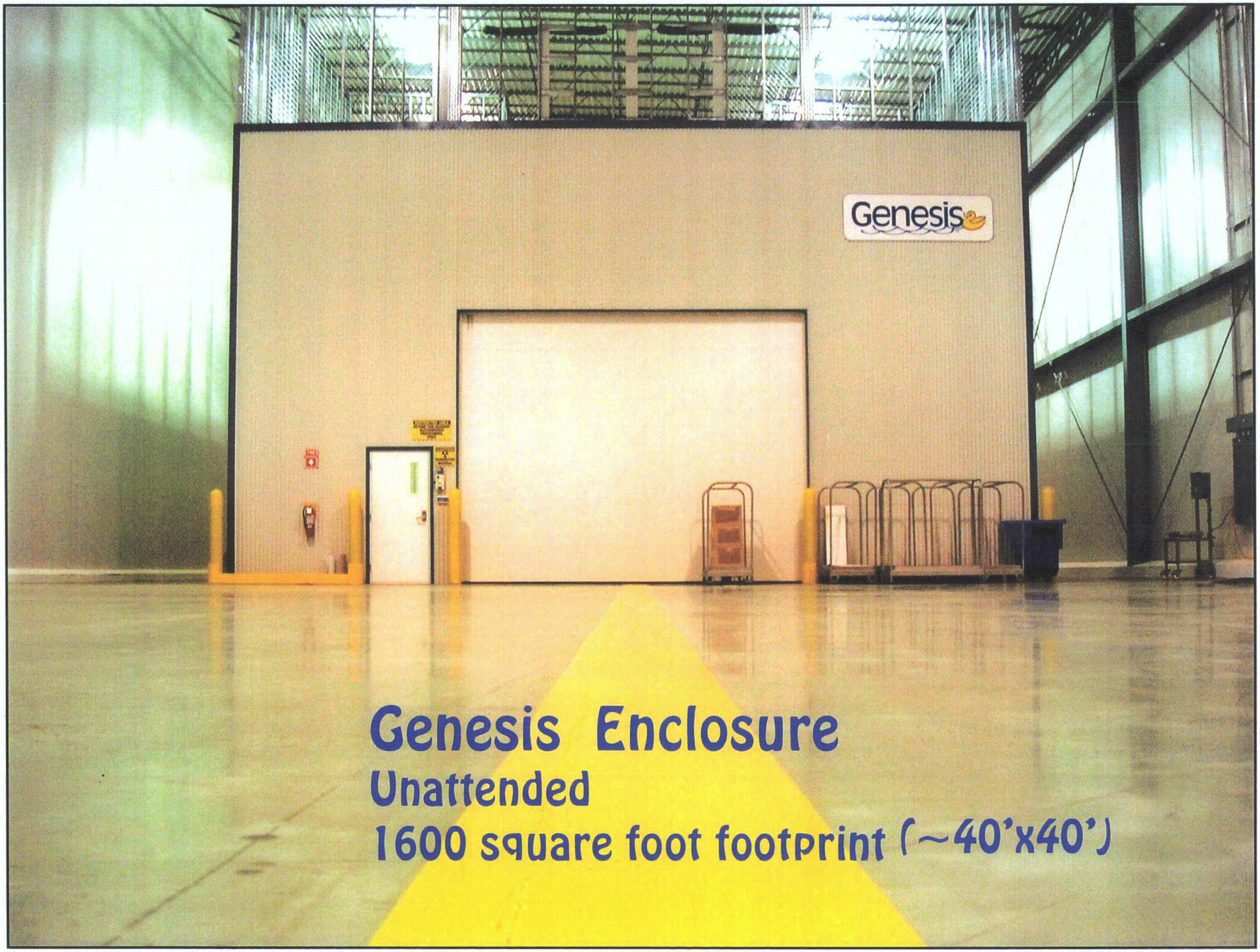
№ 470601

GRAY*STAR, Inc. Mt. Arlington Corporate Center 200 Valley Road Suite 103
Mt. Arlington, New Jersey 07856 USA Phone: (973) 398-3331 Fax: (973) 398-8310


Genesis
RESTRICTED AREA
BEYOND THIS DOORWAY
AUTHORIZED
PERSONNEL
ONLY
CAUTION
RADIOACTIVE
MATERIAL

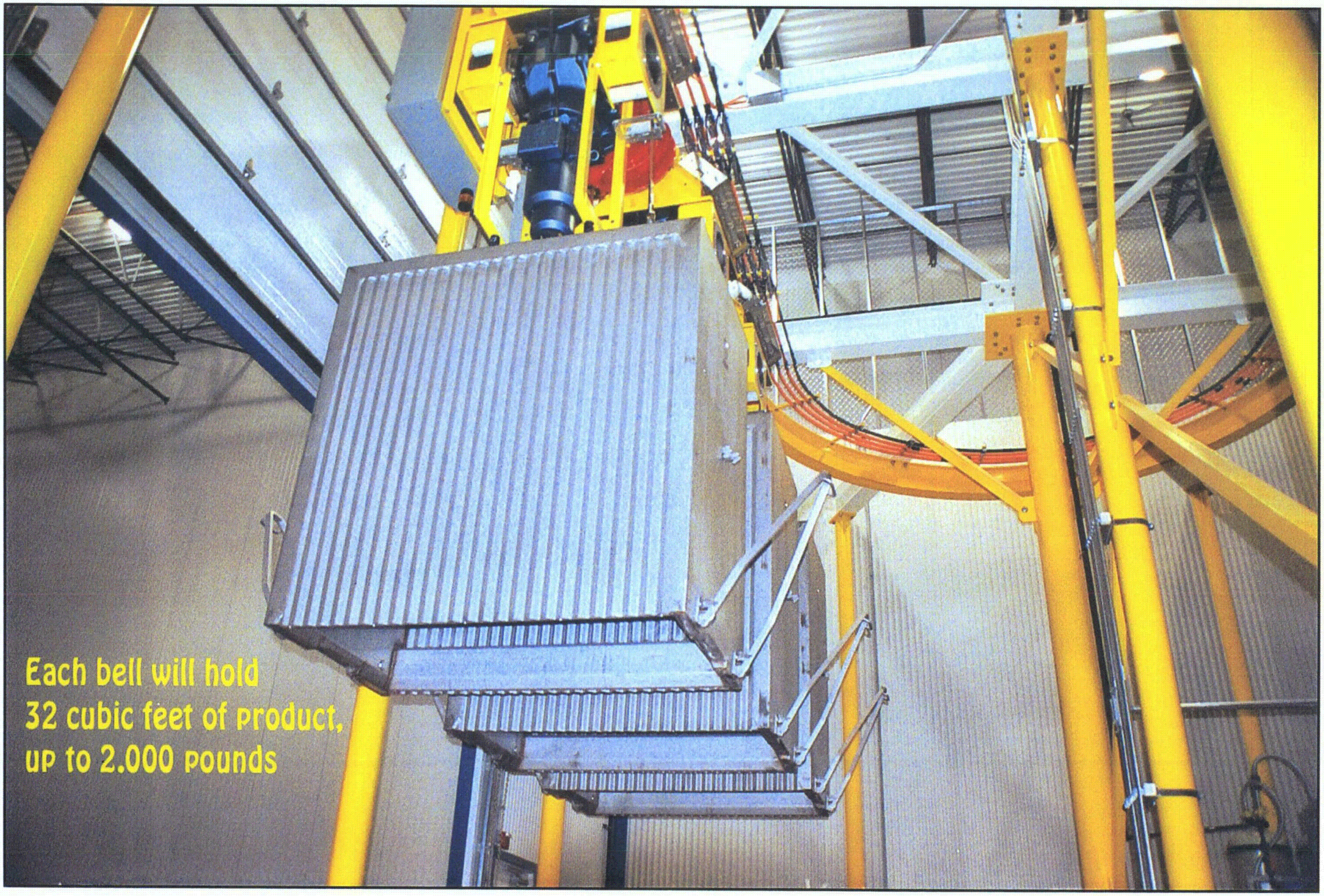

Overview


First Genesis Installation
CFC Logistics
Quakertown, Pennsylvania
CFC LOGISTICS



Genesis
Genesis Enclosure
Unattended
1600 square foot footprint (~40'x40')


3 Bells
3 Hoists


Each bell will hold
32 cubic feet of product,
up to 2,000 pounds

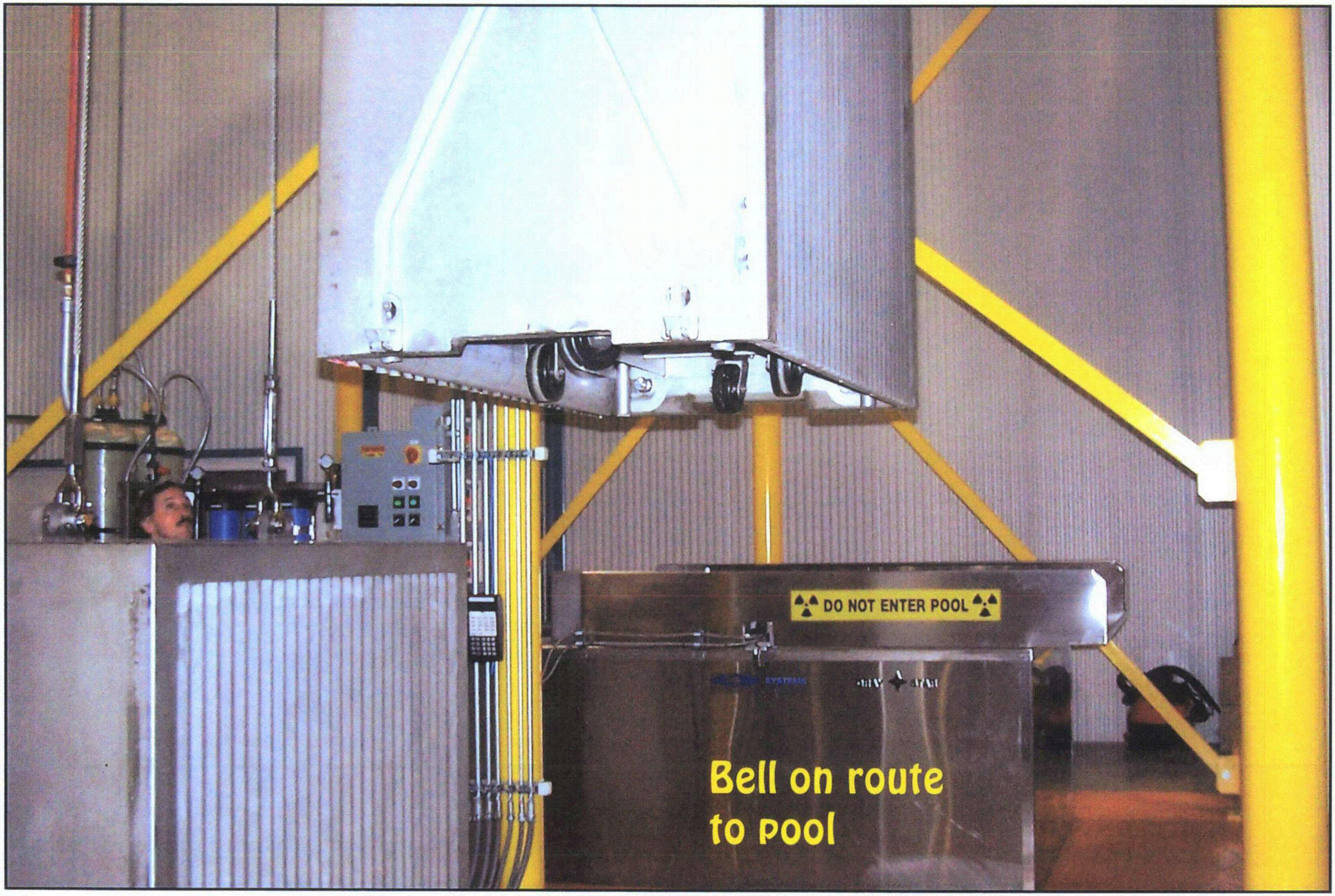
Loading product on carts

Cart is taken to loading
station in the irradiator

DO NOT ENTER POOL
SYSTEMS
Operation is controlled from console. Only one operator is required per shift.

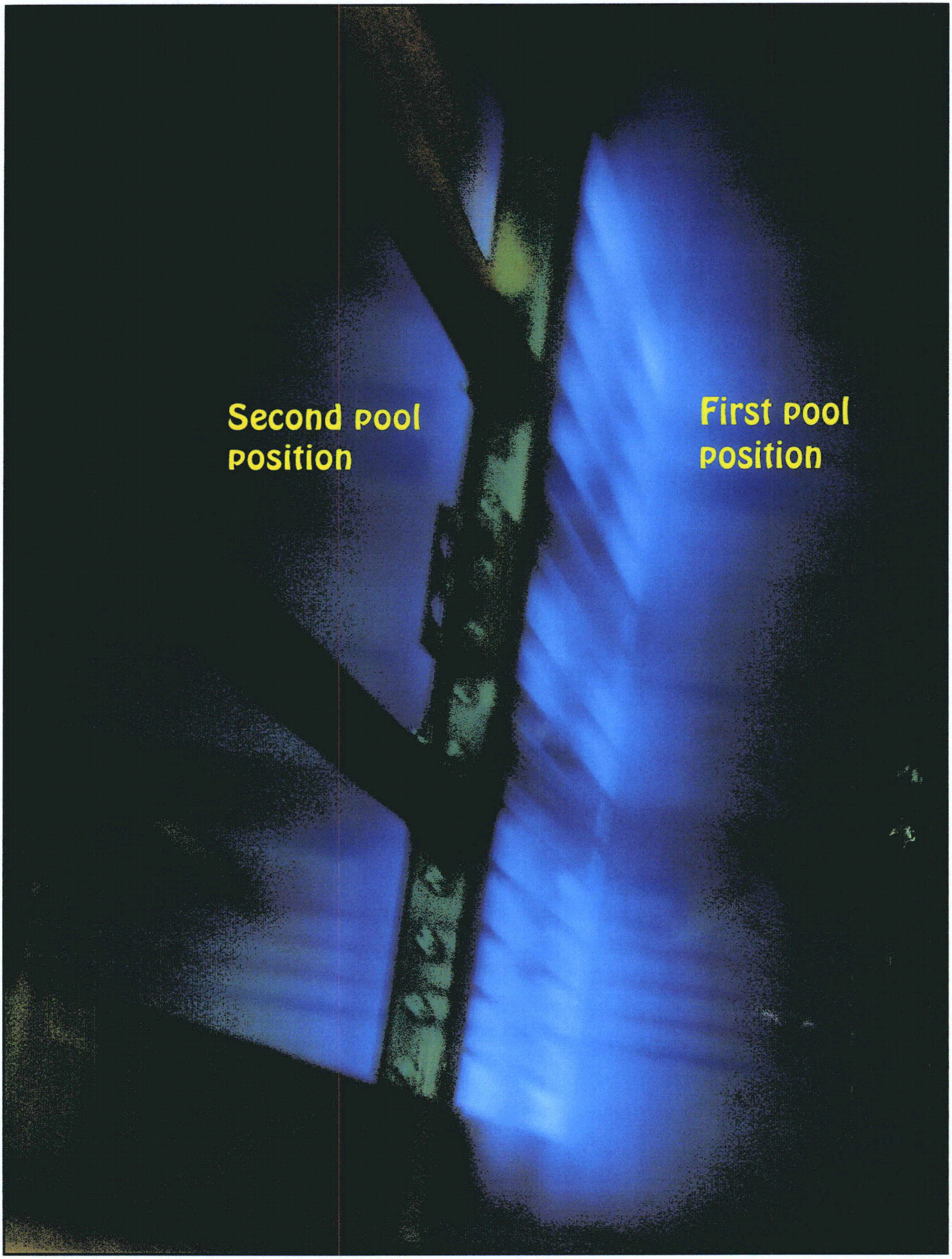

Bell lowers and
engulfs both the
product and the cart

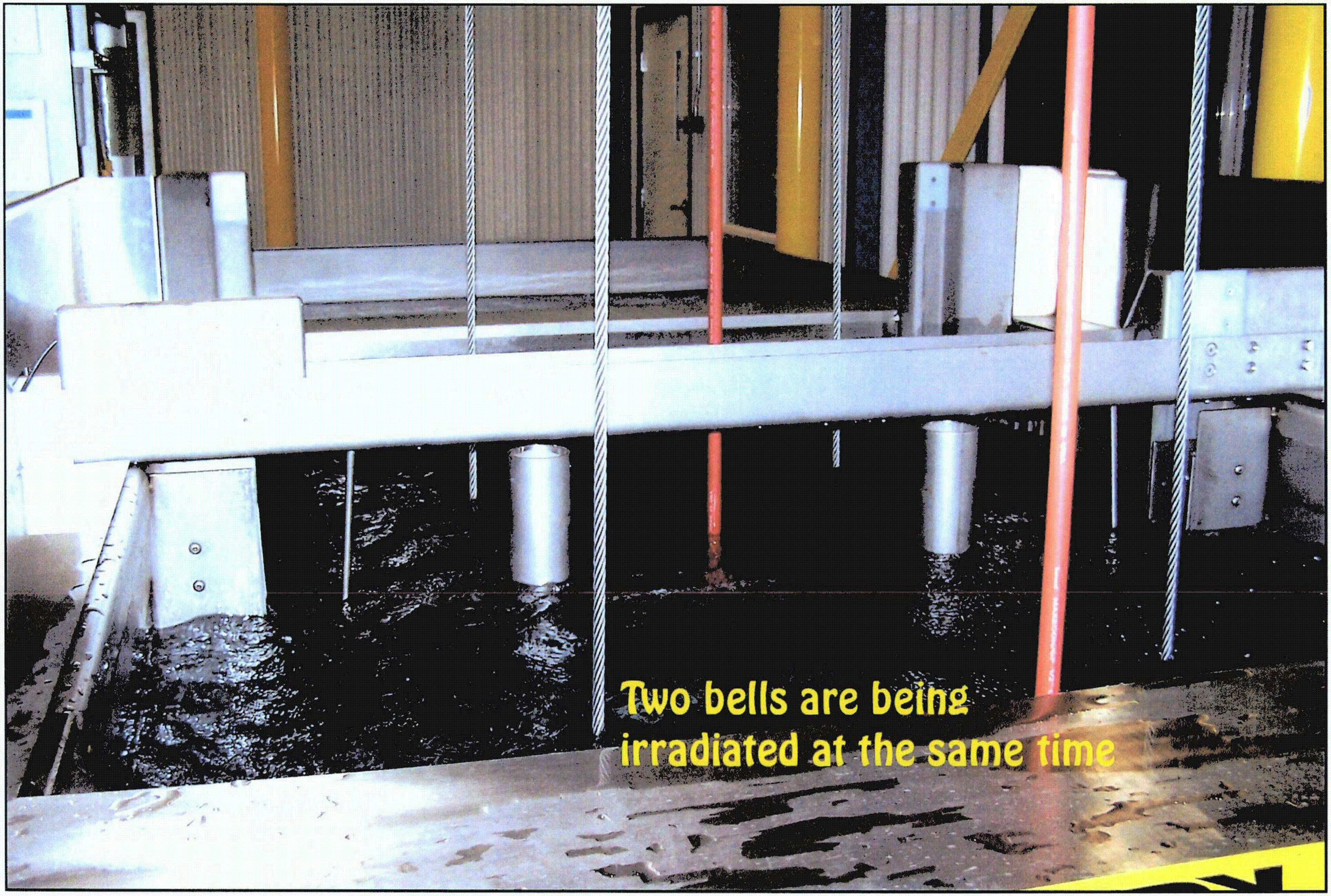

Hoist lifts bell containing
the product and moves it
into position over the pool

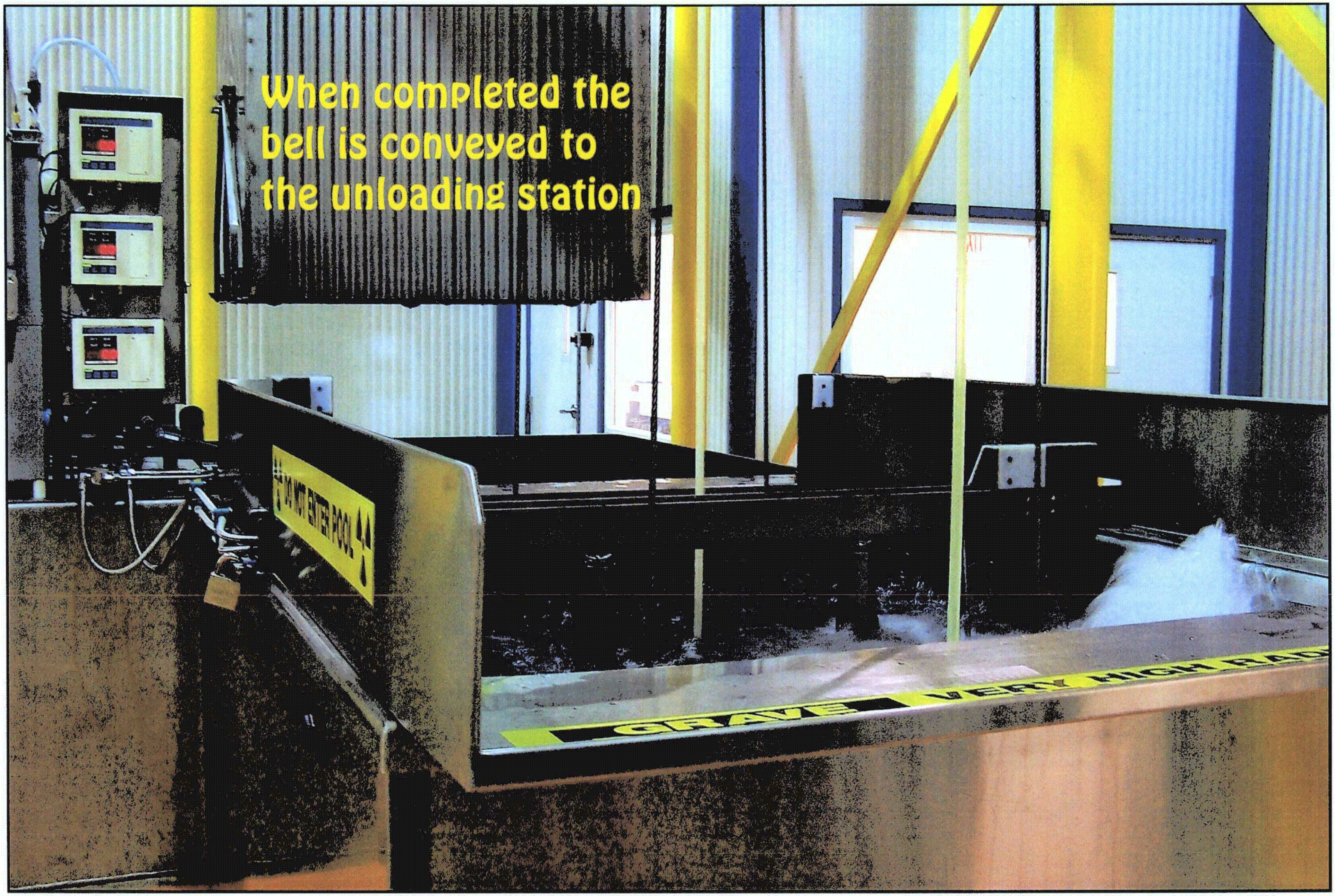

DO NOT ENTER POOL
Bell on route
to pool


First bell enters
pool. Control by
computer.
DO NOT ENTER POOL
3


First bell moves to second pool position
Next bell moves to first pool position
DO NOT ENTER POOL
GRAY STAR

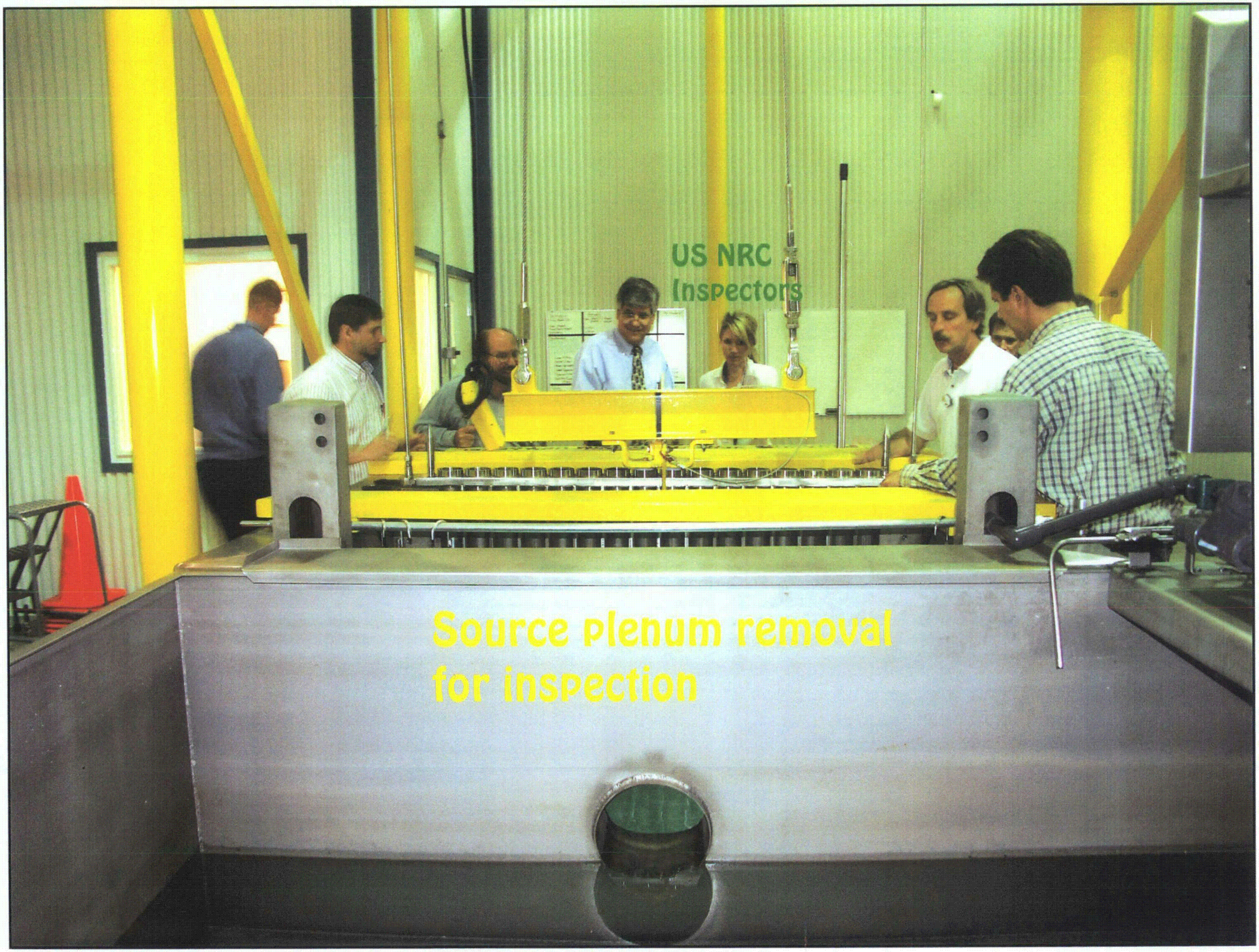

Second pool
position
First pool
position

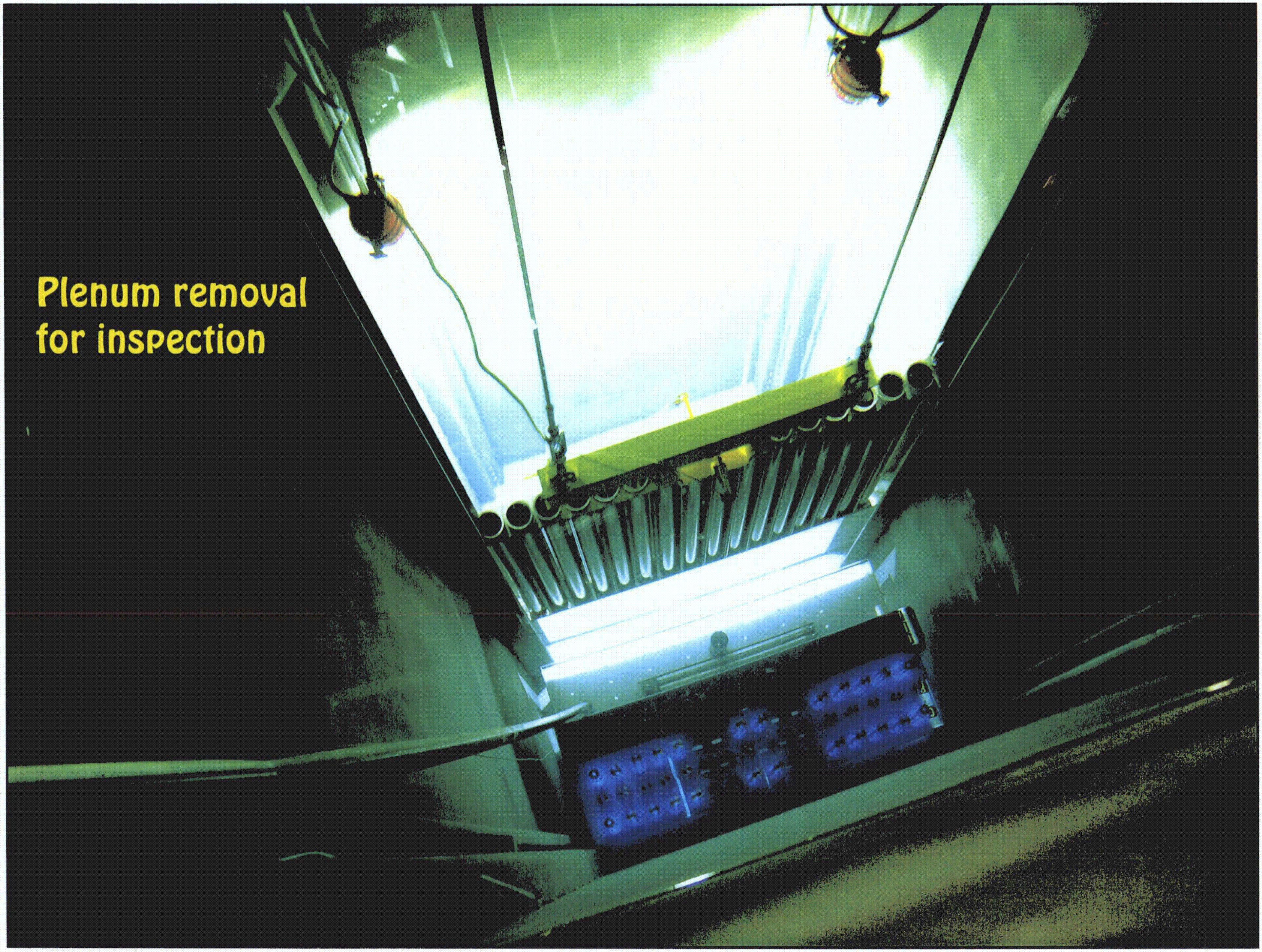

Two bells are being
irradiated at the same time

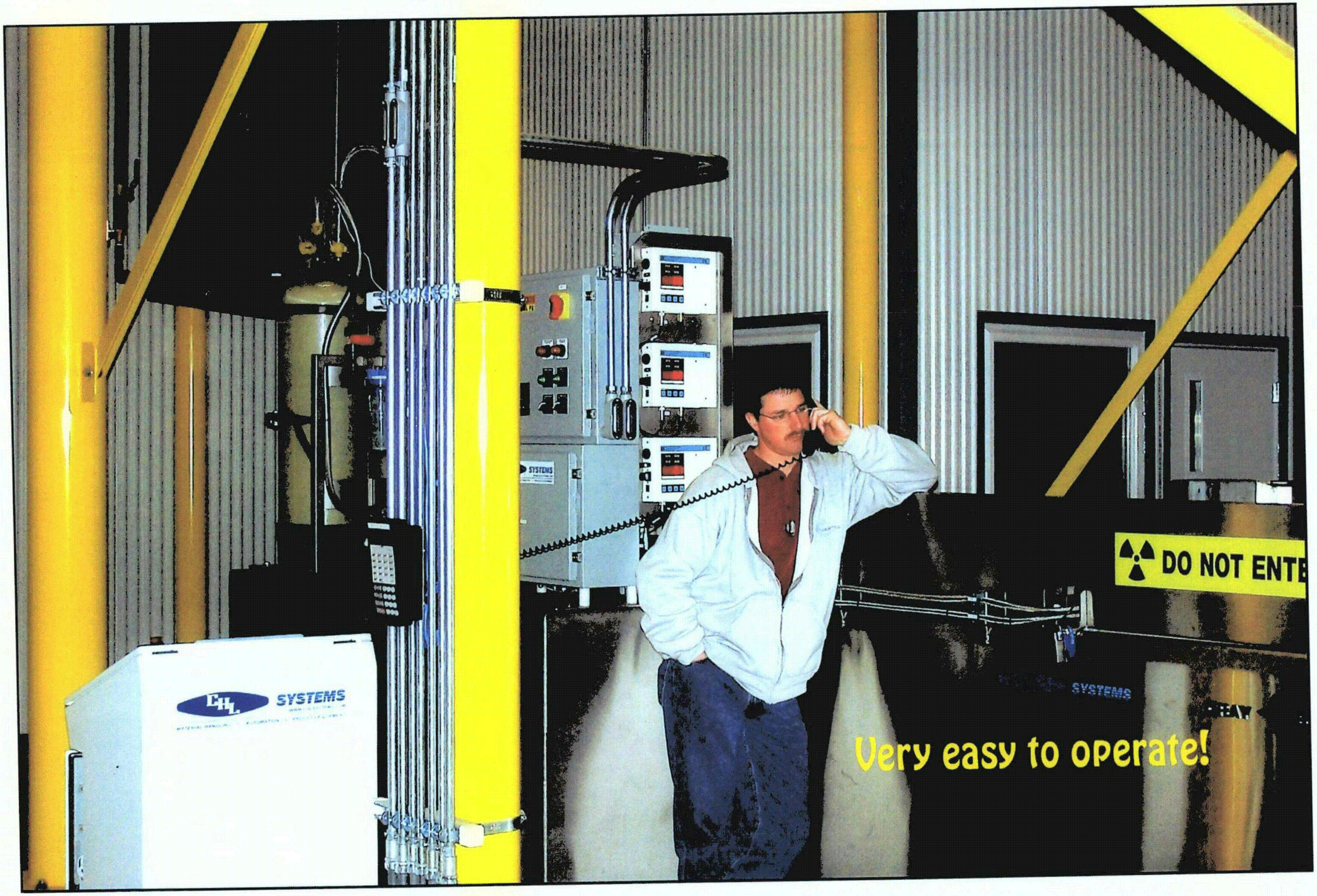

When completed the
bell is conveyed to
the unloading station
DO NOT ENTER POOL
GRAVE
VERY HIGH


Each bell weighs 3 tons, empty.
When underwater, compressed air enters the bell, keeping the product dry.
I

Water and Air Purification Systems


US NRC
Inspectors
Source plenum removal
for inspection


Plenum removal
for inspection


SYSTEMS
DO NOT ENTE
SYSTEMS
Very easy to operate!


Genni
GRAY*STAR
Mascot
Genesis
www.GrayStarInc.com

Harnessing new technology

The core of Clemens Family Corp.'s recent diversification is a Cobalt-60 food irradiator

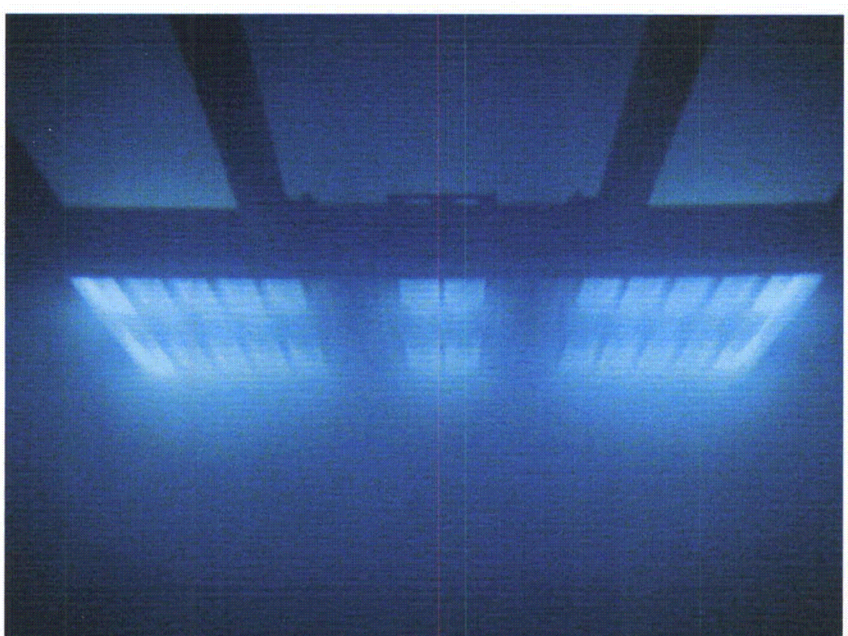
The parent corporation of Hatfield Quality Meats is rolling the dice in anticipation of the FDA's approval of irradiation of RTE products, and in the process is putting itself in the unique position of being the first corporation to own both processing and irradiation operations.

In November, CFC Logistics, a unit of Clemens Family Corp., began treating product in its new $13 million, 4.4 million-cubic-foot cold storage facility near Quakertown, Penn. What's new about the Quakertown facility is the integration of a Cobalt-60 irradiator that is relatively inexpensive to build (about $3 million, roughly one-third the cost of other irradiators) and has a relatively small footprint. According to CFC Logistics Corp. President Jim Wood, it is the first practical, self-contained gamma irradiator specifically designed to process food.

"Having an irradiator located within a cold storage/logistics operation provides a unique service opportunity for food companies in the Northeast that want to irradiate their food and perishable products to kill food-borne illnesses such as E coli O157:H7," Wood says. "This would allow us a unique opportunity to create synergies between the irradiation services and cold storage. The country's only other refrigerated irradiation facilities are in Florida and Iowa."

The timing of the new operation coincides with FDA consideration of extending the use of food irradiation for ready-to-eat meat, which industry analysts say would give the Clemens family an early lock on that end of the market because of Hatfield's meaty RTE operations.

"We're cognizant of that, but we also know, because of some of the activist campaigns, there is the risk that meat irradiation might not exactly set the world on fire either," says Chairman Phil Clemens. "But this risk is mitigated by the fact that irradiation of existing markets, like spices and botanicals would still support profitable irradiation operations for us."



CFC Logistics' new Cobalt-60 irradiator is smaller and cheaper than competitors', and is the first gamma irradiator specifically designed for food.

How it works

Unlike E-Beam or X-ray irradiators, CFC's unit does not require massive above-ground shielding or complex electrical interlock systems. The Cobalt-60 radiation source never leaves a shielded pool of water. Instead of lifting the source out of the pool into a shielded chamber, the product is lowered into the pool adjacent to the source. Air pressure in bells surrounding the product keep the product dry, and the unit treats both fresh and frozen foods in packaging up to 24 inches thick.

Product is moved into the pool by special product containers (bells) via an overhead hoist and trolley system. At the bottom of the pool the product is irradiated in a stationary position on two sides of a fixed dry plenum that contains the source of radiation.

Despite some highly publicized protests by activist group Public Citizen, the CFC irradiator has caught the attention of executives from Hormel and Cargill Meat Solutions, who have traveled to the plant, inspected the operation and talked with the manufacturer of the system—Gray Star Inc., of Mount Arlington, N.J.

"If we've got the attention of [Cargill Meat Solutions President] Bill Buckner and [Hormel CEO] Joel Johnson, it makes us feel we made a solid decision," says Clemens.

—Daniel J. Yovich, executive editor

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Frost & Sullivan Honors GRAY*STAR, Inc. with 2004 Product Innovation Award

SCOTTSDALE, Ariz.--(BUSINESS WIRE)--07/26/2004--Based on its recent study, U.S. Food and Beverage Processing Equipment Market, Frost & Sullivan presented GRAY*STAR, Inc. with the 2004 Product Innovation Award in appreciation for its Genesis Irradiator(TM) that solves longtime challenges faced by the food industry.

The Frost & Sullivan Award for Product Innovation is presented each year to the company that has demonstrated excellence in developing new products and technologies within their industry.

GRAY*STAR's revolutionary Genesis Irradiator(TM) is specifically designed to meet the needs of the food processing industry, and also serves as a cost effective solution to its customers.

"Since the Genesis Irradiator(TM) is self-contained and installed within the customer's facility, food processing companies have been able to eliminate the transportation costs associated with conventional irradiation equipment," says Frost & Sullivan Industry Manager Sanjiv Bhaskar.

The Genesis Irradiator(TM) is a competitively priced gamma irradiator that can be purchased at $1.6 million. Competitive X-ray, E-Beam and gamma irradiators can cost between $6 million to $15 million.

Moreover, the Genesis Irradiator(TM) does not require expensive safety features such as massive concrete shielding or complicated interlocks to protect the workers from radiation, which adds to the cost of the equipment.

In the Genesis Irradiator(TM), the source of radiation is placed at the bottom of the pool of water, where the product is irradiated in a stationary position on two sides of a fixed dry plenum. The pool of water acts as a unique radiation shield for protecting employees.

The Genesis Irradiator(TM) has the advantage of having a significantly smaller footprint than competitive units. The Genesis Irradiator(TM), including office and support space, occupies only 1,600 square feet as compared to more than 10,000 square feet for its competitors' equipment.

"Compared to the competition, The Genesis Irradiator(TM) is much lower in terms of bot costs and area requirements, and requires minimal support equipment," notes Bhaskar.

The Genesis Irradiator(TM) is considered a cut above the competition due to its ability tc the benefits of shorter manufacturing lead-times. While competitors take as much as twc half years to get the equipment operational, the Genesis Irradiator(TM) can be installed operational within six months.

About GRAY*STAR, Inc.

GRAY*STAR, Inc. is a privately held company. It was founded in 1989 with a single objec Design, engineer, manufacture and market irradiators that specifically meet the needs of food industry. The founders of GRAY*STAR, Inc. have been leaders in the radiation indus its inception over 40 years ago. They realized a decade ago that food irradiation would s come of age mostly because of increasing concern over foodborne disease. They also rea that an entirely new type of irradiator technology would be needed to meet the requirem the food industry. Hence the Genesis Irradiator(TM) was created.

For further information, visit www.GrayStarInc.com.

About Frost & Sullivan

Founded in 1961, Frost & Sullivan is a global leader in growth consulting. Frost & Sullivai are presented to companies that demonstrate excellence in their industry, commending t diligence, commitment, and innovative business strategies required to advance in the glc marketplace. Frost & Sullivan rigorously analyzes specific criteria to determine award rec in a vast variety of market industries and landscapes.

For further information, visit www.frost.com.

CONTACT:Frost & Sullivan, San Antonio Lori E. Donch, 210-247-2417 ldonch@frost.com
GRAY*STAR, Inc. Martin H. Stein, 973-398-3331 GrayStarGenesis@aol.com

SOURCE: Frost & Sullivan

07/26/2004 08:45 EASTERN

Food Irradiation ...
Making it Happen in Your Country

By Martin H. Stein, President, GRAY*STAR, Inc.

I've spent the last 46 years of my life extolling the virtues and benefits of food irradiation. Yet the application of this technology has been agonizingly slow. Considering just how effective and safe this technology is for sanitary and phytosanitary application, one has to wonder why it has taken so long to be adopted. There are three principal reasons for this:

1. Concern over consumer acceptance.
2. Massive and slow regulatory approvals.
3. Lack of practical equipment.

Consumer acceptance has never actually been a problem, but many people believed that it was. We now know from direct widespread sales experience that well over half of the consumers, worldwide, will purchase food that has been irradiated. This number grows even higher with appropriate education. We also know that 10-15 percent of the consumers will never purchase irradiated food because the technology offends them, much the same way that meat offends vegetarians.

Regulatory approvals have indeed been slow in coming, and that will continue for some time to come. The reason? Our governments want to show that they are working hard to protect us. Since they believe that the consumer would be afraid of consuming irradiated food they increase the regulatory hurdles to demonstrate their concern. This has begun to change with the realization that irradiating food will prevent illness and save lives. The question is no longer whether irradiated food is safe, but rather why we are not irradiating food to make it safe.

The third problem, the lack of practical equipment, is only now being resolved. Ionizing radiation is a form of electromagnetic energy similar to radiant heat and light, and as such, has physical, chemical and biological effects on materials. Many of these effects have been developed into useful processes. Probably the most notable example is the sterilization of disposable medical devices. Over the last four decades commercial irradiation facilities have evolved for the irradiation of these and other similar materials. And, it is truly an international business. Over half of all the disposable medical devices manufactured in the world are radiation sterilized. Much of the spice consumed worldwide is also sanitized by employing these same irradiators. Unfortunately, these conventional centralized irradiation facilities are simply not practical for the irradiation of perishable refrigerated food.

First, they do not suit the logistic pattern required for the production and distribution of perishable food. To keep processing costs down they must process very large product volumes. This requires very large centralized units. The resulting shipping costs to and from these large irradiators seriously exceed the cost of irradiation. Medical devices and spices have a high value for their weight and therefore can tolerate these costs, but perishable foods cannot.

Second, perishable food must be kept cold. These large centralized radiation facilities are very difficult to refrigerate, because they require massive in-cell product inventories. It can be done, but it is expensive and troublesome.

Third, conventional facilities employ complex conveyors, large water purification systems and safety interlock equipment that require strong infrastructure support. Both the quantity and the quality of electric power may be a problem, especially in remote areas. Because operators have to enter the radiation chamber from time to time, the regulatory agencies pay a great deal of attention to safety systems and operator training. This slows down and increases the regulatory approval and inspection processes. These large facilities require a fairly long time for approval and construction, since they usually require the construction of a new building to house them. The typical time for approval and construction is 2 1/2 years.

Last, but certainly not least, is the cost. The initial capital investment for the entire centralized facility is from six million to twelve million US dollars. It is quite difficult for investors, including governments, to risk that much capital for initially processing a relatively small amount of material during market startup. In other words, several years could pass, requiring a great deal of working capital, before the market builds and the investor can recover their investment.

Several years ago, GRAY*STAR, Inc., aware of these problems, designed an entirely new type of commercial perishable food irradiator. We call it the Genesis Irradiator.

The Genesis is not a "facility", but a piece of equipment, which can easily be installed within an existing building. The entire irradiator can be shipped to the site on two Sea Containers. Instead of lifting the radiation source from the shielding pool into a heavily shielded above-ground chamber, the product containers are lowered into the pool, adjacent to the radiation source. Yes, the product remains dry. Because it is a batch-continuous system it does not require a massive complex product conveyor, and the in-cell inventories are small. Temperature control is not a problem. The typical irradiation cycle time for treating meat to reduce foodborne pathogens is about 15 minutes. The phytosanitary treatment of fruit would require approximately 9 minutes. The unit takes up very little valuable floor space; about 150 square meters. Although physically small, a Genesis Irradiator, will process about 23,000 metric tons of meat per year for pathogen reduction; 32,000 metric tons of fruit for phytosanitation.

"For those of us who have spent a lifetime of effort on food irradiation it has been very frustrating, and for the most part not always rewarding. But, the major obstacles are now behind us. The way is clear. Time to move forward and build on what has been done. I wish you good fortune!"

If greater production volumes are desired more irradiator units may be added in a modular fashion.

The entire time required from the date of the initial order to becoming fully operational is less than six months. The unit is designed to operate 8000 hours per year with very little maintenance. The irradiator is inherently safe. During operations the radiation source is never raised from the pool. As a result, regulatory licensing is simpler and operators do not require as much training. All of the equipment that requires maintenance is located above the pool, outside of the radiation field, and can be routinely serviced by local personnel. Where the power supply is questionable, an optional auxiliary generator can supply the entire unit. The Genesis is supplied as a complete "kit" (minus the cobalt-60 source), including cask and source handling tools as well as the necessary radiation monitors and survey meters. With the order of a unit, a model license application will be provided along with a complete set of operational procedures, training and maintenance manuals. The present (2004) Genesis Irradiator price is US$1,600,000.

For the first time practical equipment is available. That hurdle has been overcome.

For those of us who have spent a lifetime of effort on food irradiation it has been very frustrating, and for the most part not always rewarding. But, the major obstacles are now behind us. The way is clear. Time to move forward and build on what has been done. I wish you good fortune! ■

CHRISTOPHER H. SOMMERS
Acting Research Leader
Food Safety Intervention Technologies Research Unit
U.S. Dept. of Agriculture/Agricultural Research Service
Eastern Regional Research Center
Wyndmoor, PA 19038
csommers@errc.ars.usda.gov

Food Irradiation Is Already Here

Irradiation of food and agricultural products is currently allowed by about 40 countries. Approximately 60 commercial irradiation facilities are operating in the United States.

Many food scientists and technologists are unaware that the "food irradiation industry" is only a small part of a much larger industrial group dedicated to radiation processing. Every two years, the International Meeting on Radiation Processing (IMRP) convenes, and presentations are made on the radiation processing of materials, medical and pharmaceutical products, cosmetics, and vaccines, advances in irradiation technology and facilities, radiation dosimetry, and more.

Irradiation of food and agricultural products is currently allowed by about 40 countries.

The collection of papers presented at IMRP-2003, published in *Radiation Physics and Chemistry* (Vol. 21, No. 1-2, 2004), is 606 pages long. The papers cover irradiation of spices, nutraceuticals, seafood, meat and poultry, and fruits and vegetables for inactivation of bacterial pathogens and parasites and phytosanitary purposes.

In 1997, the Food and Drug Administration approved the use of ionizing radiation to inactivate pathogenic bacteria in red meat. While some scientists and public health officials are frustrated by the slow pace with which irradiated ground beef is penetrating the U.S. market, I question whether that frustration is warranted. Many food scientists forget that it took almost 50 years for pasteurized milk to be accepted by the public in the U.S.

At this year's IFT Annual Meeting + Food Expo®, Ron Eustice of the Minnesota Beef Council reminded us that processors such as CFC Logistics, Food Technology Services, and the Institute for Food Science and Engineering at Texas A&M University are still supplying irradiated meat and poultry to thousands of stores across the U.S., even after the demise of Surebeam Corp. In September 2004, Wegman's Food Markets, Inc., announced that *Huisken BeSure*™ irradiated beef patties are available at supermarkets in New York, New Jersey, and Pennsylvania. Thus, irradiated meat and poultry have not gone away.

Although introduced too late in the 2004 school year to allow orders to be placed, irradiated ground beef was made available, on a voluntary basis, as part of the National School Lunch Program administered by USDA's Agricultural Marketing Service and Food and Nutrition Service. Within the last year, the Child Nutrition Improvement and Integrity Act was amended to codify the procurement, labeling, and educational programs already developed by AMS and FNS for irradiated ground beef. Most important, Congress mandated that "States and school food service authorities are provided model procedures for providing factual information on the science and evidence regarding irradiation technology. . . ."

The word "factual" is critical to the education process concerning irradiated foods. At USDA/ARS's Eastern Regional Research Center in Wyndmoor, Pa., we investigate an array of thermal and nonthermal intervention technologies to improve the microbiological safety and quality of foods; these include high-pressure processing, radiofrequency electric fields, competitive microbial exclusion, UHT pasteurization, and vacuum–steam–vacuum surface treatment. Unlike the private sector, we do not promote the use of specific technologies, such as irradiation, over others that would achieve the same objective. In other words, we are objectively and comparatively evaluating the efficacies of a whole range of intervention technologies.

That being said, here are the facts surrounding irradiation of ground beef: (1) Irradiation can inactivate pathogenic bacteria occasionally found in ground beef such as *Escherichia coli* O157:H7, *Salmonella*, *Staphylococcus aureus*, and *Listeria monocytogenes*. (2) Irradiation of food, including ground beef, does not make food radioactive. (3) Irradiation, when used appropriately, does not change the aroma, taste, aftertaste, texture, or overall liking of ground beef, including frozen ground beef supplied as part of the National School Lunch Program. (4) There is no detectable increase in the risk of cancer associated with long-term consumption of radiation-pasteurized meat as determined by multi-species, multi-generation feeding studies conducted in animals. (5) Irradiated ground beef is nutritious and wholesome. And (6) irradiation is only effective as part of a comprehensive program designed to improve the microbiological safety of ground beef, not to "clean up" unacceptable product.

The Scientific Status Summary that appears in this issue of *Food Technology* is an in-depth analysis of the history, potential health benefits, and future of food irradiation. As scientists and technologists, we have a responsibility to ensure that educational materials provided to the public regarding food safety and processing technologies are based on sound science. The Scientific Status Summary meets the goal of providing factual information regarding food irradiation. ●

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Print

Breaking News on Food & Beverage Development

Previous page : Food irradiation, ongoing support from IFT

Food irradiation, ongoing support from IFT

19/11/2004 - **Leading food science body the Institute of Food Technologists (IFT) defends the oft-criticised use of food irradiation in food production, brushing away criticisms that this technology could harm human health.**

Food irradiation is a proven, beneficial method of improving the safety of the food supply and poses no human health threat, said the non profit group, the IFT, in a recent article.

"The summary supports the use of this technology as a means to inactivate pathogens, maintain quality, and increase shelf life, as part of an effective overall food processing management system," writes the organisation.

Irradiation, used to prolong the shelf life of food products and/or to reduce health hazards, is a physical treatment of food with high-energy, ionising radiation. Although an accepted manufacturing process in the USA and approved for use since 1963 to control mold and insect infestation in wheat and to inhibit the growth of sprouts on potatoes, the European consumer remains sceptical of the food safety aspect.

Currently, in Europe each country has its own recommendations for the application of irradiation on foods. These vary greatly from country to country, the most liberal being France and Belgium where a variety of foods, including frog's legs and de-boned chicken, can be treated with irradiation. In other countries, such as the UK and Germany, only dried herbs, spices and vegetable seasoning can use this processing technology.

The future of food irradiation in Europe lies in the hands of the European Commission, which is the only legislator in Europe with the power to approve new food categories for irradiation. The only food category it currently lists as suitable for treatment throughout the European Union is dried herbs, spices and vegetables.

The IFT report, published this month in *Food Technology* counters 'misleading claims that irradiation produces worrisome carcinogenic byproducts, is harmful to the environment, substantially reduces food macro- and micro-nutrients, or that its use allows for sloppy practices elsewhere in the food processing line.'

At the same time, the report calls for new research to focus on: pathogen reduction protocols allowing for standards in pathogen control levels; inactivation of viruses in ready-to-eat foods and minimally processed fruits and vegetables; irradiating packaged meals; packaging advancements affecting sensory attributes.

A clear sign that the US is more willing to embrace the technology, last year the US government funded a National Center for Electron Beam Food Research at Texas A&M University, primarily to look at the benefits of electron beam technology to use electricity as an energy source for irradiating foods to kill dangerous microorganisms.

"After more than 40 years of research, declared a safe food preservation process by FDA and supported specifically by American Medical Association, the Institute of Food Technologists, American Dietetic Association, the World Health Organisation and many other organisations - food irradiation is here to help fight foodborne disease," said Dr McLellan, director of the new centre.

If the research work carried out at the A&M University can convince experts in Europe that the process is safe then the centre's work could be pivotal to the more widespread implementation of the process in Europe.

Irradiation and Food Safety

This Scientific Status Summary reviews recent activity surrounding food irradiation as a food safety measure and addresses the issues of concern for consumers, activists, and government.

J. Scott Smith, Ph.D., and Suresh Pillai, Ph.D.

Food irradiation is the process of exposing food to a controlled source of ionizing radiation for the purposes of reduction of microbial load, destruction of pathogens, extension of product shelf life, and/or disinfestation of produce. Irradiation has received approval for use in several food categories from the United States Food and Drug Administration (FDA) and has been proven as an effective food safety measure through more than 50 years of research. Yet, food irradiation continues to generate controversy, inhibiting broad acceptance and use.

In recent years, the U.S. food industry has made great advances toward improving the safety of our nation's food supply. A recent report from the Centers for Disease Control and Prevention revealed the incidence of *Escherichia coli* O157:H7 infections are down 36% from 2002 to 2003 (CDC, 2004). Despite this, foodborne diseases continue to present unacceptable public health risks that have generated the need for still further improvements in food safety, a need that is stimulated by increased public awareness of food safety issues. The purpose of this Scientific Status Summary is to review recent activity surrounding food irradiation as a food safety measure and address the issues of concern for consumers, activists, and government in an effort to further greater understanding of this promising technology.

Importance of Food Safety

The presence of microbial pathogens on human foods is a serious global problem. Even in highly industrialized and developed countries like the United States, pathogen-contaminated foods and the resulting health and economic impacts are significant. According to CDC (2004), each year Americans suffer 76 million infections, 325,000 hospitalizations, and approximately 5,000 deaths due to pathogen-contaminated foods. These events carry an estimated annual healthcare cost totaling $7 billion (USDA/ERS, 2000). Consider also that more than 74 million lb of pathogen-contaminated meat and meat products were recalled between 2000 and 2003 (USDA/FSIS, 2004), and the need for pathogen reduction is clear.

Author Smith is Professor of Food Chemistry, Dept. of Animal Science & Industry, Kansas State University, 208 Call Hall, Manhattan, KS 66506, and author Pillai is Professor of Food Safety & Environmental Microbiology and Director of the National Center for Electron Beam Food Research, Texas A&M University, 418D Kleberg Center, College Station, TX 77843-2472. Both are Professional Members of IFT. Send reprint requests to Marcia Bruxvoort at 312-782-8424 or mabruxvoort@ift.org.

Food pathogens enter the food supply through various extrinsic sources, such as fecally contaminated irrigation water supplies, farm workers, and food-processing plants. They may also enter via intrinsic routes, such as meat and meat products contaminated with pathogens (*E. coli* O157:H7, *Salmonella*, and *Campylobacter* spp.), in which case the pathogen source is the gastrointestinal tract of the slaughtered animal. A survey conducted by the U.S. Dept. of Agriculture's Food Safety and Inspection Service (USDA/FSIS, 1998) revealed that more than 97% of young turkey carcasses were contaminated with one of five pathogens, including *Campylobacter* spp., *Clostridium perfringens, E. coli* O157:H7, *Staphylococcus aureus*, and *Listeria monocytogenes*. For the most part, these pathogens are either part of the animal's normal microflora or are inevitable colonizers, and any amount of *preharvest* pathogen prevention strategies may not totally prevent contamination. The Hazard Analysis Critical Control Point (HACCP) system has been shown to greatly reduce the prevalence of pathogens (USDA/FSIS, 1999); however, improved processing technologies, such as irradiation in combination with HACCP, can further advance *postharvest* food safety.

Science of Irradiation

More than 50 years of research has gone into our understanding of the safe and effective operation of irradiation as a food safety measure—more than any other technology used in the industry today. Food irradiation employs controlled amounts of ionizing (having sufficient energy to create positive and negative charges) radiation to destroy bacteria, pathogens, and pests in food and agricultural products, greatly reducing the threat of foodborne disease. CDC experts estimate that irradiating half of all ground beef, poultry, pork, and processed meat would reduce food poisoning by one million cases and prevent 6,000 serious illnesses and 350 deaths (Tauxe, 2001).

Ionizing radiation includes gamma rays (from radioactive isotopes cobalt-60 or cesium-137), beta rays generated by electron beam or "E-beam," and X-rays. None of these irradiation sources has sufficient energy to be capable of inducing radioactivity; however, they do have enough energy to remove electrons from atoms to form ions or free radicals. The freed electrons collide with chemical bonds in the microbial DNA molecules, thereby breaking them and rendering the microbe dead. The amount of ionizing radiation absorbed is termed radiation absorbed dose and is measured in units of rads (1 rad=100 erg/g) or grays (1 Gy=100 rads), with 1 gray equal to 1 Joule/kg and 1,000 grays equal to 1 kiloGray (kGy). The level of microbe reduction is dependent on the dose absorbed by the target food (Olson, 1998). Gamma rays and X-rays are able to penetrate further into foods than beta rays; therefore, E-beam generators arranged to deliver electrons from one side can penetrate about 1.5 in in food; two-sided treatment can achieve maximum penetration, up to about 3.5 in (GAO, 2000).

Ionizing radiation can damage the nucleic acids and ultimately kill microbes by direct or indirect "hits." In the case of an indirect hit, damage to the nucleic acids occurs when the radiation ionizes an adjacent molecule, which in turn reacts with the genetic material. Because water is the largest component of most foods and microbes, it is often the adjacent molecule that ends up producing a lethal product (Grecz et al., 1983). Ionizing radiation causes water molecules to lose an electron, producing H_2O^+ and an electron. These products react with other water molecules to produce a number of compounds, including hydrogen and hydroxyl radicals (OH$\cdot$), molecular hydrogen, oxygen, and hydrogen peroxide (H_2O_2) (Arena, 1971). Hydroxyl radicals and hydrogen peroxide are very reactive and are known to interfere with the bonds between nucleic acids within a single strand or between opposite strands. Though biological systems do have a capacity to repair both single-stranded and double-stranded breaks of the DNA backbone (Bartek and Lukas, 2003), the damage occurring from ionizing radiation is random (Razskazovskiy et al., 2003) and extensive. Therefore, bacterial repair of radiation damage is a near impossibility.

The relative sensitivity of different microorganisms to ionizing radiation is based on their respective D_{10} values (which is the dose required to reduce the population by 90%). Lower D_{10} values indicate greater sensitivity of the organism in question. The data in Table 1 shows that minimal doses can achieve significant gains in food safety.

Microbial cells, whether pathogenic or comprising the normal microflora of foods, exhibit differences in their responses to ionizing radiation. The key factors that control the resistance of microbial cells to ionizing radiation are the size of the organism (the smaller the target organism, the more resistant it is to ionizing radiation), type of organism (i.e., cell-wall characteristics and gram positive or gram negative in nature), number and relative "age" of the cells in the food sample, and absence or presence of oxygen. The physical and chemical composition of the food also affects microbial responses to irradiation. For example, as the temperature of ground turkey is decreased from 30°C to –30°C (Table 1), the D_{10} value increases from 0.16 kGy to 0.29 kGy. D_{10} values change as the water in the product freezes, thereby decreasing the rate of migration of

Table 1—D_{10} values for specific pathogens on meat and egg products. Adapted from Molins (2001).

Target organism	Temperature (°C)	Product	D_{10} value (kGy)	Reference
Staphylococcus aureus	5	Turkey breast meat	0.45	Thayer et al. (1995)
Campylobacter jejuni	30	Ground turkey	0.16	Lambert and Maxcy (1984)
	5		0.19	
	–30		0.29	
Salmonella Heidelberg	0	Poultry (air packed)	0.24	Licciardello et al. (1970)
	0	Poultry (vacuum packed)	0.39	
Salmonella Enteriditis	5	Egg powder	0.6	Matic et al. (1990)
	3	Ground beef	0.55–0.78	Tarkowski et al. (1984)
Salmonella spp.	5	Turkey breast meat	0.71	Thayer et al. (1995)
Listeria monocytogenes	5	Beef	0.45	
Escherichia coli O157:H7	5	Ground beef patties	0.27–0.38	Lopez-Gonzales et al. (1999)

the ionization products, including free radicals, and requiring greater energy input to cause the collisions necessary to destroy the microbes (Thayer, 2004).

Effectiveness and Benefits of Irradiation

Aside from the obvious improvements in food safety through destruction of pathogens, irradiation provides other benefits. Some of these contributions include increasing shelf life of meats (Murano et al., 1998; Thayer, 1993) and fruits and vegetables (Thayer and Rajkowski, 1999); improving quality of fruits and vegetables (Thayer and Rajkowski, 1999); providing a suitable alternative to chemical treatments (e.g., methyl bromide and ethylene oxide), especially for decontamination of fruits and vegetables (Thayer and Rajkowski, 1999); and providing economic savings due to reduced incidence of illness. Despite these added benefits, this technology remains vastly underutilized in the food industry.

Issues Confronting Widespread Use of Irradiation

Several extensive reviews of toxicological and other data by regulatory and health organizations, including Health Canada (2003), FDA (1986), Codex Alimentarius Commission (CAC, 1983), and European Commission's Scientific Committee on Food (EC, 2003), have determined that food irradiated below 10 kGy is safe. More recently, the CAC (2003) revised slightly its General Standard for Irradiated Foods, stating that the maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose.

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In 1999, a joint study group of the U.N.'s Food and Agriculture Organization (FAO), International Atomic Energy Agency (IAEA), and World Health Organization (WHO) concluded that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate. The group also concluded that no upper limit on absorbed dose was necessary because use of irradiation would be limited to doses that do not detrimentally impact the sensory attributes, thus creating a practical cut-off at about 50–75 kGy (WHO, 1999). The group's report included all pertinent animal feeding studies (82 in total), mutagenicity studies (47 in vitro), and food type and test species through 1997. Although 14 studies showed an effect, the cause was attributed in each case to a diet/nutrient deficiency, not irradiation. It is important to remember that these trials involved feeding diets containing significant amounts of food items (average 35%–100%) irradiated at very high doses, often to 59 kGy. There were eight possible effects of high-dose radiation observed in the mutagenicity studies. Two of the studies involved feeding irradiated oils, which apparently caused extensive oxidation and loss of carotenoids. The other six studies used irradiated simple sugar solutions (e.g., sucrose, fructose, glucose, etc.) that are now known to involve formation of mutagens by radiation-induced chemical mechanisms (Fan, 2003).

In 1976, the U.S. government contracted Raltech Scientific Services to carry out comprehensive nutritional, genetic, and toxicological studies of food irradiation. Mice, hamsters, rats, and rabbits were fed chicken (as 35–70% of their diet) that had been irradiated at a minimum absorbed dose of 46 kGy. Dogs, rats, and mice were also fed the irradiated chicken at 35% of their diet during multigenerational studies. They found no evidence of genetic toxicity or teratogenic effects in mice, hamsters, rats, or rabbits and no treatment-related abnormalities or changes in the multigenerational studies (Thayer et al., 1987).

• **Radiolytic Products.** During the last 25 years (since the advent of gas chromatography/mass spectrometry, GC/MS), numerous volatile compounds have been isolated from irradiated products. The vast majority (more than 70%) of the radiolytic volatile compounds found in irradiated foods are hydrocarbons, such as alkanes, alkenes, ketones, and aldehydes, that are commonly found in unprocessed and thermally processed foods (Hannisdal, 1993; Morehouse et al., 1991; Nawar et al., 1990) and are considered safe for human consumption.

Two groups of compounds have generated concern. They are benzene (and its derivatives) and alkylcyclobutanones (ACBs). The Federation of American Societies for Experimental Biology evaluated 65 compounds found in beef and noted that small amounts of benzene could be detected in both irradiated (15 ppb) beef (56 kGy) and non-irradiated (3 ppb) beef (Chinn, 1979). This expert committee concluded that such small amounts of benzene do not constitute a significant risk. Health Canada's Bureau of Chemical Safety reached a similar conclusion upon evaluation of an application for irradiated ground beef (Health Canada, 2002). Health Canada estimated that approximately 3 ppb of benzene would be formed in beef irradiated at the typical dose ranges (1.5–4.5 kGy). This level of benzene was noted to be much lower than naturally occurring levels in haddock (200 ppb) and eggs (average 62 ppb) (McNeal et al., 1993). Thus, the risk of benzene exposure from irradiated foods is considered negligible.

ACBs were first identified in irradiated fats due to the pioneering work of LeTellier and Nawar (1972). When pure triglycerides containing C6, C8, C10, C12, C14, C16, and C18 fatty acids were subjected to irradiation (60 kGy in vacuum), 2-substituted ACBs (2-ACBs) were formed having the same number of carbon atoms as the acids from which they were derived. Thus, when the four major fatty acids present in most foods (palmitic, stearic, oleic, and linoleic acid) are irradiated, they are converted to their corresponding cyclobutanones, 2-dodecyl (2-DCB), 2-tetradecyl (2-TCB), 2-tetradecenyl (2-TDCB), and 2-tetradecadienyl cyclobutanone (2-TDeCB). As yet, these ACBs have not been found in raw or heat-processed foods and are considered unique radiolytic products (Crone et al., 1992a; Stevenson, 1994).

• **Mutagenic/Genotoxic Studies.** Current discussions on the potential mutagenicity of irradiated foods have centered on the work of Burnouf et al. (2002), which has shown that the radiolytic compounds originating from 2-ACB fatty acids appear to induce DNA damage under unique experimental conditions. Cell cultures were evaluated for toxicity when exposed to concentrations of up to 400 μMolar. Cytotoxicity was observed in some cultures at 50 μM, with most ACBs exhibiting toxicity at 100 µM. Genotoxicity of the cultures was measured with the DNA Computerized Molecular Evaluation of Toxicity (Comet) assay after a 30-min exposure and no significant differences were found. DNA strand breaks in two different cell lines were also measured with ACB concentrations of up to 40 ppm (90 for 2-TCB). The effects seem to appear at 10 ppm for some ACBs, though cell death that starts at 25 ppm may confound the data and call it into question. With one of the cell lines there appeared to be fewer DNA breaks than controls at low levels of ACBs (10 ppm). The breaks increased with concentration; however, there was extensive cell death at the higher levels (Delincée and Pool-Zobel, 1998).

Raul et al. (2002) induced colon cancer in rats with azoxymethane (AOM) injection and then fed either 2-TDCB or 2-TDeCB (50 ppm) in drinking water ad libitum. Tumor development was followed for 27 weeks post injection. The total number of colon preneoplastic lesions was the same for all treatments, indicating that the cyclobutanones did not increase colon lesions. The only significant differences were that the treated animals developed larger lesions and a greater number of larger tumors. These findings are suspect, however, because each treatment group contained only six animals, which is probably insufficient to draw conclusions, and there was not a dose-dependent response. Also, the control animals, which received ACB in the drinking water, did not develop lesions unless they had been preinjected with AOM.

Another study measured the recovery of dietary 2-TCB and 2-TDCB included in the daily feed of rats (Horvatovich et al., 2002). After four months of feeding, no 2-TDCB was recovered. Small amounts of 2-TDCB were recovered in the feces (1%), and only a trace amount was found in the adipose tissue (0.3 ppm). The authors concluded that the lack of recovery was a concern. If the cyclobutanones were catabolized via some oxidative mechanism to some type of water-soluble lactone, then it would have been quickly eliminated or metabolized for energy production. Thus, metabolism, a desirable outcome of consumption, may suggest a lack of toxicity.

Health Canada (2003) released an evaluation of the ACB genotoxic data, expressing the opinion, similar to that of the EC's Scientific Committee on Food (EC, 2002), that the Comet test was inappropriate because it does not perform well for weak agents, of which the 2-ACBs would qualify, and is not "validated or adequately standardized." They also found that the concentrations of 2-DCB tested were very high compared to human consumption levels. Based on the levels of 2-DCB measured by Burnouf et al. (2002) in chicken (0.342 mg/g lipid/kGy) and ground beef (0.409 mg/g lipid/kGy) and the average consumption by Canadians, Health Canada calculated that the amount of 2-DCB ingested via chicken and via ground beef would be 8,500 and 10,000 times lower, respectively, than the lowest dose deemed to elicit a Comet response. Other researchers have reported lower 2-DCB levels in irradiated beef, pork, and chicken—0.2 mg (per g of lipid) when processed at 1 kGy and 1–1.2 mg (per g of lipid) at 5 kGy (Stevenson, 1994), which would further dilute the value of the Comet assay.

The EC's Scientific Committee on Food released a revision of its 1986 opinion on food irradiation that addressed the ACB toxicity concerns (EC, 2003). It was the consensus of the committee that the genotoxicity of ACBs had not been established because there was no mutagenic effect in the Ames test or in standard cell lines. Burnouf et al. (2002) and Gadgil and Smith (2004) have evaluated cyclobutanones for their mutagenic potential using the classical Ames test. No mutagenicity was observed either with or without liver microsomal activation. Sommers and Schiestl (2004) evaluated the 2-ACBs for mutagenicity with the *E. coli* TRP assay and for a DNA-strand-induced recombination and were unable to find any 2-ACB effects.

Gadgil and Smith (2004) also found that 2-DCB was of low toxicity in the Microtox assay with *Vibrio fischeri* cells. Their results indicated that 2-DCB is similar in toxicity to the food additive cyclohexanone (which has Generally Recognized as Safe status), and was 10-fold less toxic than *t*-2 nonenal, a normal constituent of cooked ground beef and an approved food additive (GRAS status flavorant), indicating that 2-DCB has very low toxicity and does not warrant concern.

• **Vitamin and Nutrient Losses.** In general, macronutrient (protein, lipid, and carbohydrate) quality does not suffer due to irradiation (Thayer, 1990; Thayer et al., 1987; WHO, 1999), and minerals have also been shown to remain stable (Diehl, 1995).

There is a fair amount of concern over the effect of irradiation on other micronutrients, especially vitamins. In most studies, vitamins have been shown to retain substantial levels of activity post irradiation. Vitamins A, C, and E are more sensitive and are thereby reduced at higher doses of irradiation, even though these losses are often similar to those occurring with thermal processing. Vitamin E is the most sensitive of the fat-soluble vitamins with significant losses (50%) occurring when irradiated in the presence of oxygen. When oxygen was excluded or vacuum packaging was used, the losses were less than 10% (Josephson et al., 1975). Significant losses were shown to occur in cream cheese (vitamin A)when air was not excluded (Diehl, 1979) and in fruits and vegetables (vitamin C) treated with high doses. However, these findings are irrelevant because high-dose radiation is not used for such products.

Thiamine (vitamin B1) has been shown to be the most vulnerable to radiation and is therefore used to demonstrate "worst-case" results (WHO, 1994). Significant losses can occur in irradiated meat products (Fox et al., 1995; Graham et al., 1998; Thayer, 1990). However, the extent of such losses is dependent on processing conditions (temperature and dose) and can be minimized using packaging techniques (Fox et al., 1997). Meats, with the exception of pork, do not make major dietary contributions to B1 intake (Subar et al., 1998). Therefore, FDA and Health Canada have determined that even with high irradiation doses, thiamine intake would still be above its recommended dietary allowance. FDA has concluded that the effects of irradiation processing on nutrient quality are similar to those of conventional food-processing methods.

• **Sensory Changes.** Foods such as milk, certain cheeses, eggs, and some fruits and vegetables are not likely candidates for irradiation because of the potential for undesirable off-odors, flavors, and texture changes (WHO, 1999). The bulk of sensory work has focused on muscle foods, because most of the emphasis for this technology has been on these foods (Molins, 2001).

Two groups have evaluated ground beef under various conditions of radiation dose (0–4.5 kGy), temperature (–25°C to room temperature), and packaging (Murano et al., 1998; Vickers and Wang, 2002). These researchers have shown that irradiation causes no significant differences in the flavor, texture, or color of beef irradiated at less than 3 kGy (Murano et al., 1998; Vickers and Wang, 2002).

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Luchsinger et al. (1996) evaluated acceptance of fresh or frozen irradiated boneless pork chops at 1.5, 2.5, and 3.85 kGy using a trained panel and consumers (n=108). They found no significant differences in acceptance, meatiness, freshness, or juiciness in products irradiated at 2.5 kGy or below.

However, some researchers have shown that poultry and pork are sensitive to flavor and color (pinking) changes (Houser et al., 2003; Nam and Ahn, 2002). Several studies have been published recently to address this issue. Process techniques (packaging and antioxidants) that improve these meat characteristics are being evaluated (Bagorogoza and Bowers, 2001; Nam et al., 2004) and, in at least one instance, consumers have shown preference for the pink color (Lee et al., 2003).

Although there have been fewer studies with fruits and vegetables, the use of low-dose irradiation as a countermeasure to quarantine (due to pest infestation) and/or for extension of shelf life is promising. Follet and Sanxter (2002) studied the tropical fruits and found papayas, rambutans, and Kau oranges were acceptable when treated with a quarantine level of 0.75 kGy (minimum dose required is 0.25 kGy). They also found Chompoo and Biew Kiew fruit to be more acceptable when treated with 0.40 kGy than with the currently used hot-water immersion. Due to restrictions on chemical treatments and the increasing demand of imported products, application of low-dose irradiation has become an active area of research.

Concerns expressed by Anti-Irradiation Groups

• **Misuse to Avoid Plant Sanitation.** A common concern stated by those opposed to food irradiation is that it would be used as an alternative to proper food-processing plant sanitation and cleanliness practices. A similar argument was used to dissuade implementation of milk pasteurization in the early 1900s. Today, milk pasteurization is a commonly used practice proven to have prevented countless illnesses due to milkborne salmonellosis (Satin, 1996). Heavily contaminated food requires higher doses that would have a negative impact on the acceptability of the product. Using food irradiation to overcome inadequate sanitation practices, or irradiating only selected lots or batches of food (having documented pathogen presence) with radiation doses, would be counter productive and serve as a death knell to this food processing technology. Food irradiation is intended as the final step of a comprehensive HACCP program.

• **Environmental Concerns.** There are lingering concerns among opponents to food irradiation regarding the environmental safety of irradiation facilities. Issues surrounding use, safety, and exposure to radioactive materials are often promoted as a concern relative to food irradiation, while similar concerns have not been major issues pertaining to the use of irradiation to sterilize medical equipment and other healthcare products (Derr, 1993). Regulation of irradiation facilities is dependent on the source used. Gamma facilities have specific characteristics to protect workers (regulated by the Occupational Safety and Health Administration) and the surrounding environment from the radioactive isotopes and for storing the isotope material under water when not in use, which are regulated by the U.S. Nuclear Regulatory Commission. Cobalt-60, the isotope used in such facilities, requires 16–21 years to decay to approximately 6–12% of its initial activity level, at which time it is shipped back to the manufacturer in hardened steel shipping canisters to be regenerated and reused. Unlike gamma facilities, E-beam and X-ray do not employ radioactive sources and thereby avoid such issues. They do contain a significant amount of electrical circuitry, cooling systems, worker safety systems, and ozone attenuation capabilities (Olson, 1998). These facilities are regulated by FDA and by state agencies that regulate other medical, dental, and industrial devices.

Production of ground-level ozone from E-beam facilities has also been cited as a concern. Ozone is produced when the accelerated electrons come into contact with air and is routinely exhausted when interior levels reach maximum continuous exposure levels. It must be emphasized that there are state and federal rules governing ozone emissions by industrial facilities. The National Ambient Air Quality Standards have set the upper emission limit at 0.12 ppm/hr (40 CFR 50.9). Thus, E-beam irradiation facilities are not permitted to operate if ozone emissions exceed this limit.

State of the Technology

• **Regulatory Summary.** FDA evaluates irradiation as a food additive on the logic that it affects the characteristics of the food or becomes a component in the food; however nothing is physically added to the food. Other processes such as baking, frying, boiling, etc., cause chemical changes in the food and they are not considered additives, but processes. Regardless, the United States currently has the most widespread approvals for the use of irradiation for food (Table 2).

FDA labeling requirements call for inclusion of the radura, which is the symbol developed to signify a food having been irradiated. Also, the words "treated with radiation" or "treated by irradiation" must be printed on the package, unless the word "irradiated" is part of the product name (21 CFR 179.26).

In Canada and Europe, approvals are more limited. Canada has issued approvals for use on potatoes, onions, spices, dehydrated seasonings, wheat, and flour (Health Canada, 1989). The addition of poultry, beef, shrimp, prawns, and mangoes to the Health Canada approved list has been in the approval process since 2002 and was expected to receive approval in the first half of 2004 (Dalpe, 2004). Until 1999, use in Europe varied from country to country; however, due to concerns among the EU member states, the European Parliament has issued directives to establish a community list. The current list contains only dried aromatic herbs, spices, and vegetable seasonings (EC, 1999). EC (2003) issued a report reconfirming its resistance to expansion of this list. A lack of breadth of the human clinical studies database was cited as the reason behind this decision.

• **Market Status.** Despite its promise, irradiation is not a major factor in today's food-processing environment. According to a report released by the U.S. General Accounting Office, as of January 2000, irradiated fruits and vegetables and fresh and frozen uncooked poultry accounted for only 0.002% of annual U.S. consumption in each of their respective categories. Irradiation to preserve spices and botanicals is the largest area of application and is estimated at 9.5% of annual U.S. consumption (GAO, 2000). The report states that at that time, irradiated beef and pork products were not available commercially. Since then, irradiated beef has been placed in supermarkets; however, sales have staggered at least partly due to inconsistency in availability. In January 2004, a major irradiation company, SureBeam Corp., filed for Chapter 7 bankruptcy, prompting several grocery stores and a major fast-food chain to suspend sale of irradiated ground beef. Two other irradiation facilities, Food Technology Services, Mulberry, Fla., and CFC Logistics, Quakertown, Pa., have picked up much of that business.

• **Consumer Acceptance.** Over the years, polls have revealed acceptability rates ranging from 45% to more than 90%, depending on the food type and method of presentation (Fox, 2002). Nayga et al. (2004) published a report stating that consumers would purchase irradiated foods and are "willing to pay" premiums ranging from \$0.05 to \$0.50/lb., depending on their level of concern and awareness and the provision of sufficient background information. These findings emphasize the importance of educating the public on the controversy, the technology, and the benefits of irradiation, especially since the public has been shown to be more receptive to the negative argument (Fox, 2002; Hayes et al., 2002).

• **National Nutrition Programs.** As a result of the 2002 Farm Bill, which directs USDA to utilize any and all approved food safety technologies for food purchased through the National Nutrition Programs, irradiated ground beef became an option for school lunches in January 2004. The product comes at a premium (\$0.13–0.20/lb), and the decision to use it resides with each individual district. A letter from USDA Under Secretary of Nutrition and Consumer Services Eric Bost to school superintendents encouraged them to inform parents and children of the decision to include irradiated meat; however, USDA cannot require such action (USDA, 2003). There has been backlash to the provision of irradiated ground beef, with some districts (e.g., Washington, D.C., Berkeley, Calif., and Los Angeles, Calif.) quickly moving to prohibit its use. However, as of July 2004, 200 of the 26,000 school districts decided to purchase irradiated ground beef (Eustice, 2004).

Research Needs

• **Pathogen Reduction Protocols.** Standardization of pathogen reduction protocols is a much needed area of research. Currently there is no required "kill" such as that established for *E. coli* O157:H7 in juices (i.e., a 5-$\log_{10}$ reduction). Such standards are needed to establish global continuity and enable trade.

• **Inactivation Kinetics of Foodborne Viruses.** Enteric viruses (Noroviruses and Rotavirus) are responsible for a significant number of food-borne illnesses in the United States (Mead et al., 1999), but are generally assumed to be unaffected by radiation. Recent studies suggest that, depending on the sample matrix, viruses can become sensitive to E-beam radiation at levels significantly lower than those produced with cobalt-60 irradiation (Pillai and Espinosa, 2003). Studies are needed to identify the conditions that can eliminate viral pathogens in ready-to-eat (RTE) foods and minimally-processed fruits and vegetables.

• **Radiosensitization.** Studies show that certain chemical components, when added extraneously, can significantly reduce the D_{10} value of a particular pathogen. The precise mechanisms that are involved in this radiosensitization of microbial pathogens need to be further elucidated. A better understanding of the factors controlling the sensitization of microbial pathogens can allow for the incorporation of specific "sensitizing" molecules directly to the food, the matrix, or the packaging materials to attain or prevent a desired level of nucleic acid damage.

• **Microbial Stress Conditions and Radiation Sensitivity.** Recent studies have shown that the physiological state of the cell is critically important when evaluating its radiation resistance. Buchanan et al. (1999) reported that different strains of the same pathogen can exhibit significant differences in radiation sensitivity, presumably a reflection of their physiological status. Microbial cells in the starvation mode can also exhibit increased resistance to radiation. Since starved or moribund cells have a significantly reduced number of DNA replication forks, the potential targets for DNA damage are subsequently reduced. Stress-induced proteins and other cellular components such as lipid and protein-rich foods may either protect the cells, or enhance DNA repair under optimal conditions. Studies have also shown that carbon monoxide in MAP and hydrogen peroxide treatments can

Table 2—Irradiation applications approved or under consideration by FDA and USDA. Adapted from Olson (1998).

Product	Dose (kGy)	Purpose	Date
Wheat, wheat flour	0.2–0.5	Insect disinfestations, mold control	1963
White potatoes	0.05–0.15	Sprout inhibition	1964
Pork	0.3–1.0	*Trichinella spiralis*	1985
Enzymes (dehydrated)	10.0 max.	Microbial control	1986
Fruit and vegetables, fresh	1.0 max.	Disinfestation, ripening delay	1986
Herbs, spices, vegetable seasonings	30.0 max.	Microbial control	1986
Poultry, fresh or frozen	3.0 max.	Microbial control	1990
Poultry, fresh or frozen (USDA)	1.5–4.5	Microbial control	1992
Meat, frozen, packaged[a]	44.0 min.	Sterilization	1995
Animal feed and pet food	2.0–25.0	*Salmonella* control	1995
Meat, uncooked, chilled	4.5 max.	Microbial control	1997
Meat, uncooked, frozen	7.0 max.	Microbial control	1997
Meat, uncooked, chilled (USDA)	4.5 max.	Microbial control	2000
Meat, uncooked, frozen (USDA)	7.0 max.	Microbial control	2000
Fresh shell eggs	3.0 max.	*Salmonella* control	2000
Seeds for sprouting	8.0 max.	Microbial control	2000
Molluscan shellfish, fresh or frozen	0.5–7.5	*Vibrio, Salmonella, Listeria* control	1999, pending
Ready-to-eat, unrefrigerated meat and poultry products	4.5 max.	Microbial control	1999, pending
Certain refrigerated, frozen, or dried meat, poultry, or vegetable products	4.5 max.	10.0 max.	Microbial control 1999, pending

[a]For meats used only by NASA space flight programs.

also protect microorganisms from ionizing radiation to varying degrees.

The precise mechanism of protection or repair needs to be elucidated so that appropriate strategies (e.g., microbial hurdle techniques) can be adopted when irradiating such foods. A number of other stress factors, such as osmotic stress, heat stress, and alkali stress, can also enhance radiation resistance. Thus, when D_{10} values are established for specific foods, the possibility that these factors (in addition to the physical state of the food matrix) may influence the behavior of pathogens and indigenous organisms must be taken into consideration.

• **Organoleptic Attributes.** There is an urgent need for standardization to evaluate sensory changes or organoleptic attributes of irradiated products as they relate to radiation sources, irradiation conditions, dosimetry, and product profiles. Without such standardization, it would be difficult to compare and analyze irradiation results. There is also a need to objectively characterize and quantify adverse or positive changes in these attributes analytically.

• **Multi-Component Foods.** Once federal approvals for RTE foods are obtained, there will be a significant set of opportunities to use food irradiation for multi-component foods, such as RTE meals. The issues of dosimetry, pathogen reduction, and sensory will be extremely significant in these types of foods because of the anticipated differences in the food matrix, potential varying pathogen loads, types of pathogens that could be encountered, and the critical need to retain the sensory attributes of the packaged meals.

• **Product Packaging.** Research is needed on the next generation of packaging materials to retard negative sensory attributes or enhance desirable ones. The combination of modified-atmosphere packaging (MAP) and irradiation has been reported to enhance desirable changes and improve safety of sausage (Ahn et al., 2002), ground beef (Kusmider et al., 2002), turkey (Bagorogoza and Bowers, 2001), fresh-cut iceberg lettuce (Fan and Sokorai, 2002), and romaine lettuce (Prakash et al., 2000). The use of antimicrobial coatings (Vachon et al., 2003) and antioxidant additions (Lee et al., 2003) also provide avenues that could potentially extend the usage of irradiation. The development of packaging materials that can visually denote an irradiated product or dose range, or detect adverse changes in a product would also be beneficial.

A Safe and Effective Process

An overwhelming body of evidence spanning a period of more than 50 years supports the FDA determination that food irradiation can be used without posing a human health hazard and that furthermore, its use will improve the microbial safety of the food supply. This technology has been proven beneficial for not only controlling pathogens, but also increasing shelf life and maintaining food quality. Irradiation to ensure food safety is to be implemented as part of an overall HACCP plan and is not meant to replace existing control measures.

Recent attention has focused on the formation of unique radiolytic products because initial reports revealed the possibility of associated carcinogenicity. However, Burnouf et al. (2002) warned against applying their findings directly, did not find positive results for the Ames test, and used only pure ACBs in quantities much greater than those measured in actual foods. Since the release of that report, several researchers have refuted the findings of Burnouf et al. and indicated that levels in irradiated foods do not warrant a public health concern.

Food irradiation is a safe and effective process that can be used to improve the safety of our food supply.

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Edited by Cory M. Bryant, Ph.D., Research Scientist, IFT Dept. of Science and Technology Projects, cmbryant@ift.org.

INSTITUTE OF FOOD TECHNOLOGISTS

The Society for Food Science and Technology

World Headquarters: 525 W. Van Buren Street, Suite 1000
Chicago, IL 60607
Voice: 312–782–8424 • Fax: 312–782–8348
e-mail: info@ift.org • www.ift.org

Washington, D.C.: 1025 Connecticut Ave., NW, Suite 503
Washington, DC 20036
Voice: 202–466–5980 • Fax: 202–466–5988
e-mail: dcoffice@ift.org • www.ift.org

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Lewis Wolpert: 'Doctors could play an important role in food irradiation'

20 October 2004

Certain words from science have a negative effect. "Clone" is a good example. But worse is "radiation", which is associated with all sorts of evils, particularly nuclear power. This may account for the neglect of using irradiation to reduce food poisoning.

In the United States, it is estimated that there are 76 million cases of food-borne disease every year, leading to thousands of people needing hospital treatment and some 5,000 deaths.

Each year, it is estimated that up to 5.5 million people in the UK may suffer from food-borne illnesses - that's one in 10 people. Food-borne bugs in meat and poultry are major causes. Yet the irradiation of food has the potential to reduce dramatically the dangers of food poisoning.

Food irradiation is basically the same as pasteurisation of milk by heat, which can destroy nasty micro-organisms without affecting the nature of the milk. Yet there is resistance to food irradiation. Few people are aware that radiation is used to sterilise many of the products used in their homes. These include baby-bottle nipples, cosmetics and bandages.

Research on methods to control food-borne bacteria go back a long way. In 1904, there was an article in the journal *Proceedings of the Royal Society* showing that radiation from radium inactivated Staphylococcus (a parasitic bacterium that can cause boils and blood poisoning), as well as the bacteria that cause cholera and anthrax.

In 1905, a patent was issued to British merchant J Appleby for the use of radiation to improve the condition of foodstuffs. But it is only since the 1950s that the technology for commercial application has become available.

There are various arguments against the irradiation of food. One is that irradiation produces a chemical in the food that could cause cancer, even though it is present in tiny amounts. All the evidence is against this. No evidence of any negative effects were observed in studies in which animals were fed irradiated food as about half of their normal diet. Another argument is that irradiation destroys the nutritional quality of the food. But the main constituents of food, such as proteins, carbohydrates and fat, are not appreciably affected at the doses used. Both the US Food and Drug Administration and the American Dietetic Association concluded that irradiation poses no risk to any nutrient in food.

There is the claim that irradiation is a quick fix for a major problem regarding food hygiene. It is seen as an easy way for the food industry to ignore sanitation before irradiation. But even good sanitation can result in less than 1 per cent of meat from a slaughterhouse being contaminated, and in the US this would mean that some 11 million kilograms of meat are contaminated. Irradiation could prevent this. But a major aspect of resistance to its use is its association with radioactivity, and the beliefs of certain groups about interfering with nature.

Irradiation does have its problems, as it does not prevent subsequent contamination by consumers or food-service workers. There is evidence that irradiation can affect the odour, colour and texture of some foods. Also, some fruits, vegetables and dairy products have a reduced shelf-life after irradiation.

In the US, only 10 per cent of herbs and spices are irradiated and less than 0.002 per cent of other foods. In the UK, there are strict regulations about food irradiation: it is not legal for any foods, apart from herbs and spices, to be irradiated for general sale, as no company holds a licence to do so.

It may rest with the public to encourage more use of food irradiation. There was a related situation in the 1930s, when pasteurised milk was introduced. Doctors and others in the health field played an important role in getting it accepted. They could play a similar role in relation to the irradiation of food. This will not be easy. In the US, approval has been given for the irradiation of hamburgers for school lunches. But groups opposed to irradiation are claiming that the children are being used as experimental animals.

Lewis Wolpert is professor of biology as applied to medicine at University College London

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PERSPECTIVE

Irradiation of Food — Helping to Ensure Food Safety

Donald W. Thayer, Ph.D.

In this issue of the *Journal*, Osterholm and Norgan (pages 1898–1901) present a convincing argument that physicians and other health care professionals, as health advocates, should also be advocates for the irradiation of foods to prevent the transmission of infection. The recent approval of irradiated hamburgers for school lunch programs in the United States has been met with unfounded claims by groups opposed to food irradiation that children are being used as experimental animals. Unfortunately, this campaign has influenced some school boards to deny their students the increased safety of irradiated foods.

Research on methods to control foodborne pathogens and the safety of irradiated foods has a long history. In 1896, Franz Minck suggested in the *Munich Medical Journal* that x-rays might have value as therapy for disease. Then Alan B. Green reported in the 1904 *Proceedings of the Royal Society* that radiation from radium inactivated *Staphylococcus aureus*, *Vibrio cholerae*, and *Bacillus anthracis*. In 1905, a patent was issued in Britain to the merchant J. Appleby for the use of ionizing radiation to improve the condition of foodstuffs. In 1918, in Tampa, Florida, David Gillett patented a device that used a bank of 16 x-ray tubes to preserve organic materials. He specifically suggested that it be used for the inactivation of trichinae in pork, and in 1921, a scientist at the U.S. Department of Agriculture established that encysted trichinae could be inactivated by means of x-rays. In 1927, J.K. Narat conducted perhaps the first toxicologic study of irradiated food, discovering effects in mice that were eventually attributed to vitamin deficiencies in the irradiated feed, rather than to irradiation itself. Irradiated animal feeds are now used routinely during toxicologic studies of drugs.

Research accelerated during the 1950s, with the development of commercial equipment and facilities for irradiation. Further study during the past 50 years has identified many of the factors that make the process more or less effective in controlling pathogens, as well as the effects of irradiation on nutrients and on the sensory properties of foods. Toxicologic studies have been conducted with both foods that have been pasteurized through irradiation and shelf-stable foods that have been sterilized by means of irradiation. For example, no evidence of toxic genetic or teratogenic effects has been found in mice, hamsters, rats, or rabbits that were fed radiation-sterilized chicken meat as 35 or 70 percent of their total diet (as measured on a dry-weight basis). Nor were any treatment-related abnormalities or changes observed in dogs, rats, or mice that were fed the radiation-sterilized chicken as 35 percent of their total diet during multigenerational studies. The 46-kGy dose used for sterilization in these studies far exceeded the doses used to pasteurize products such as ground beef, for which the Food and Drug Administration has set a maximum of 4.5 kGy (7 kGy for frozen beef).

Research and development have continued, and today, accelerated electrons and gamma and x-ray photons are used both in the treatment of patients and to sterilize many therapeutic products. Many people are unaware that radiation is used to sterilize or treat many of the products that they use in their own homes, such as baby-bottle nipples, personal-hygiene products, cosmetics, bandages, polymerized flooring materials, Teflon-coated skillets, and insulation on electrical wire. Most spices are contaminated with 1 million or more bacteria per gram, so many commercial facilities irradiate spices. Unfortunately, irradiated foods are in limited supply in the United States, although our astronauts have been eating steaks sterilized with 45 kGy of gamma radiation since 1960.

The radiation applied to food is much more limited than that used in radiotherapy. Only two isotopic sources of gamma rays have been approved for use — cobalt-60 and cesium-137. Electron energies are limited to a maximal acceleration of 10 MeV, and x-rays generated by the electron bombardment of a metal such as tungsten are limited to 5 MeV. None of these types of radiation are capable of generating radioactivity. The choice of the most appropriate form of technology is largely dependent on the product. Electrons with a maximal energy of 10 MeV penetrate to a depth of only 4.5 cm in water or equiv-

Table. Dose of Radiation Required to Inactivate 99.9 Percent of Foodborne Pathogens in Meat or Poultry with Electron, Gamma, or X-Ray Ionizing Radiation at 5°C.

Foodborne Pathogen	Dose of Radiation (kGy)
Campylobacter jejuni	0.48–0.60
Escherichia coli O157:H7	0.84–0.96
Listeria monocytogenes	1.26–1.44
Salmonella species	1.98–2.22
Staphylococcus aureus	1.32–1.44

alent, limiting their use to thin packages or to products with very low density; however, the required dose of radiation is delivered extremely quickly. The generation of x-rays is not very efficient, since only 6 to 12 percent of the electron energy is converted to x-rays; the remainder generates heat, which must be removed before the target melts.

The absorption of electrons or of photons produces the same effect, ionization. When a gamma or x-ray photon is absorbed, an electron is released, causing ionization. Water is the principal target for the radiation, because it is the largest component of most foods and microorganisms. Normally, approximately 70 percent of the radiation-induced ionization will occur in cellular water, and the target organisms will be inactivated because of secondary reactions, not because of a direct effect on the bacterial DNA. The same sequence occurs in frozen products, but the ice structure limits the migration of the free radicals that are generated by the ionization; therefore, a higher dose of radiation is required for frozen foods. There is much greater potential to produce adverse sensorial effects in fresh products than in frozen products.

The doses of radiation that are required to inactivate 99.9 percent of a contaminating population of a few important foodborne pathogens in meat and poultry are listed in the Table. The dose required to inactivate 99.9 percent of *Escherichia coli* O157:H7 in ground beef increases from approximately 0.90 kGy at 5°C to 1.35 kGy at −5°C. Food irradiation may offer the only reliable method of controlling foodborne pathogens in ground meat or poultry without cooking. Unfortunately, a high proportion of the poultry we bring into our homes or commercial kitchens remains contaminated with one or more of the pathogens listed in the Table. Cooking will kill most of these pathogens, but the problems associated with the cross-contamination of other foods remain. Some restaurants are now using irradiated poultry to prevent such contamination, and the public would benefit from greater implementation of this method of ensuring the safety of foods.

Dr. Thayer reports having received consulting or lecture fees from CFC Logistics, Master Foods, and Zero Mountain.

From Lower Gwynedd, Pa.

Irradiation of Food — Helping to Ensure Food Safety

Donald W. Thayer, Ph.D.

In this issue of the *Journal*, Osterholm and Norgan (pages 1898–1901) present a convincing argument that physicians and other health care professionals, as health advocates, should also be advocates for the irradiation of foods to prevent the transmission of infection. The recent approval of irradiated hamburgers for school lunch programs in the United States has been met with unfounded claims by groups opposed to food irradiation that children are being used as experimental animals. Unfortunately, this campaign has influenced some school boards to deny their students the increased safety of irradiated foods.

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Research accelerated during the 1950s, with the development of commercial equipment and facilities for irradiation. Further study during the past 50 years has identified many of the factors that make the process more or less effective in controlling pathogens, as well as the effects of irradiation on nutrients and on the sensory properties of foods. Toxicologic studies have been conducted with both foods that have been pasteurized through irradiation and shelf-stable foods that have been sterilized by means of irradiation. For example, no evidence of toxic genetic or teratogenic effects has been found in mice, hamsters, rats, or rabbits that were fed radiation-sterilized chicken meat as 35 or 70 percent of their total diet (as measured on a dry-weight basis). Nor were any treatment-related abnormalities or changes observed in dogs, rats, or mice that were fed the radiation-sterilized chicken as 35 percent of their total diet during multigenerational studies. The 46-kGy dose used for sterilization in these studies far exceeded the doses used to pasteurize products such as ground beef, for which the Food and Drug Administration has set a maximum of 4.5 kGy (7 kGy for frozen beef).

Research and development have continued, and today, accelerated electrons and gamma and x-ray photons are used both in the treatment of patients and to sterilize many therapeutic products. Many people are unaware that radiation is used to sterilize or treat many of the products that they use in their own homes, such as baby-bottle nipples, personal-hygiene products, cosmetics, bandages, polymerized flooring materials, Teflon-coated skillets, and insulation on electrical wire. Most spices are contaminated with 1 million or more bacteria per gram, so many commercial facilities irradiate spices. Unfortunately, irradiated foods are in limited supply in the United States, although our astronauts have been eating steaks sterilized with 45 kGy of gamma radiation since 1960.

The radiation applied to food is much more limited than that used in radiotherapy. Only two isotopic sources of gamma rays have been approved for use — cobalt-60 and cesium-137. Electron energies are limited to a maximal acceleration of 10 MeV, and x-rays generated by the electron bombardment of a metal such as tungsten are limited to 5 MeV. None of these types of radiation are capable of generating radioactivity. The choice of the most appropriate form of technology is largely dependent on the product. Electrons with a maximal energy of 10 MeV penetrate to a depth of only 4.5 cm in water or equiv-

Table. Dose of Radiation Required to Inactivate 99.9 Percent of Foodborne Pathogens in Meat or Poultry with Electron, Gamma, or X-Ray Ionizing Radiation at 5°C.

Foodborne Pathogen	Dose of Radiation (kGy)
Campylobacter jejuni	0.48–0.60
Escherichia coli O157:H7	0.84–0.96
Listeria monocytogenes	1.26–1.44
Salmonella species	1.98–2.22
Staphylococcus aureus	1.32–1.44

alent, limiting their use to thin packages or to products with very low density; however, the required dose of radiation is delivered extremely quickly. The generation of x-rays is not very efficient, since only 6 to 12 percent of the electron energy is converted to x-rays; the remainder generates heat, which must be removed before the target melts.

The absorption of electrons or of photons produces the same effect, ionization. When a gamma or x-ray photon is absorbed, an electron is released, causing ionization. Water is the principal target for the radiation, because it is the largest component of most foods and microorganisms. Normally, approximately 70 percent of the radiation-induced ionization will occur in cellular water, and the target organisms will be inactivated because of secondary reactions, not because of a direct effect on the bacterial DNA. The same sequence occurs in frozen products, but the ice structure limits the migration of the free radicals that are generated by the ionization; therefore, a higher dose of radiation is required for frozen foods. There is much greater potential to produce adverse sensorial effects in fresh products than in frozen products.

The doses of radiation that are required to inactivate 99.9 percent of a contaminating population of a few important foodborne pathogens in meat and poultry are listed in the Table. The dose required to inactivate 99.9 percent of *Escherichia coli* O157:H7 in ground beef increases from approximately 0.90 kGy at 5°C to 1.35 kGy at −5°C. Food irradiation may offer the only reliable method of controlling foodborne pathogens in ground meat or poultry without cooking. Unfortunately, a high proportion of the poultry we bring into our homes or commercial kitchens remains contaminated with one or more of the pathogens listed in the Table. Cooking will kill most of these pathogens, but the problems associated with the cross-contamination of other foods remain. Some restaurants are now using irradiated poultry to prevent such contamination, and the public would benefit from greater implementation of this method of ensuring the safety of foods.

Dr. Thayer reports having received consulting or lecture fees from CFC Logistics, Master Foods, and Zero Mountain.

From Lower Gwynedd, Pa.

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Title: The Role of Irradiation in Food Safety

Authors: Michael T. Osterholm, Ph.D., MPH*

Director, Center for Infectious Disease Research and Policy (CIDRAP) Professor, School of Public Health University of Minnesota

Andrew P. Norgan

Research Assistant Center for Infectious Disease Research and Policy (CIDRAP) University of Minnesota

*Corresponding Author: Michael T. Osterholm, PhD, MPH Center for Infectious Disease Research and Policy (CIDRAP) C315 Mayo Memorial Building, MMC 263 420 Delaware St. S.E. Minneapolis, MN 55455 Phone: 612-626-6770 Fax: 612-626-6783 E-mail: mto@umn.edu

An estimated 76 million cases of foodborne disease, resulting in over 325,000 hospitalizations and 5,000 deaths, occur in the United States annually.[1] Important sources of foodborne pathogens include improperly cooked, handled, or stored meat and poultry products, and contaminated produce. The meat and poultry industry's current surveillance and intervention efforts have reduced, but not eliminated, microbial contamination of meat and poultry carcasses.[2,3] Despite these efforts, consumers continue to experience preventable illnesses and death caused by microbial contamination of foods. Food irradiation has the potential to dramatically decrease the incidence of foodborne disease and is widely supported by international and national medical, scientific, and public health organizations and food- processing and related industry groups (Table 1). Currently, food irradiation technology is underutilized. In the United States only 10 percent of herbs and spices and less than 0.002 percent of fruits, vegetables, meats, and poultry are irradiated.[4]

Slow growth in the acceptance of irradiation can be attributed to several factors. First, the term "irradiation" is sometimes confusing or alarming to consumers because of its apparent, but nonexistent, association with induced radioactivity. Second, the causes and prevention of foodborne disease are poorly understood by the general public. Third, health professionals and the media are largely unaware of the benefits of food irradiation. Finally, an anti-irradiation campaign has been conducted by certain groups because of their beliefs about food, nuclear power, and agricultural economics.

The Technology of Food Irradiation

Radiation is energy transmitted through space in the form of electromagnetic waves, which may considered as rays, or particles. Food irradiation utilizes high-energy radiation in any of three approved forms: gamma ray, x-ray, and electron beam. Gamma rays can be generated by either of two approved radionuclide sources, cobalt-60 and cesium-137. x-rays and electron beams are generated electrically.

Irradiation doses with respect to food processing are measured in units of Gray (Gy) or kiloGray (kGy), with 1 Gy equivalent to 100 rads. Convention divides doses into three categories by application: less than 1 kGy (low-dose) for disinfestation and shelf-life extension; 1 to 10 kGy (pasteurizing dose) for pasteurization of meats, poultry, and other foods; and greater than 10 kGy (high-dose) for sterilization or for microbial reduction in spices.[5]

Commercial use of irradiation for meats and poultry is conceptually similar to milk pasteurization. Pasteurization is defined as (1) the critical reduction of pathogens in a substance, especially a liquid (e.g., milk) at a temperature and for a period of exposure that destroys objectionable organisms without major chemical alteration of the substance or (2) the critical reduction of pathogens in perishable food products (e.g., fruit or fish) with radiation (e.g., gamma rays).[6] Heat pasteurization kills or inhibits the growth of pathogens in raw milk, but surviving nonpathogenic bacteria can eventually cause the milk to spoil if stored for extended periods of time or mishandled. Similarly, pasteurization by irradiation is not intended to completely eliminate all bacteria in meat and poultry, but rather to achieve a high probability of the elimination of pathogenic microorganisms.[7]

Thus, irradiation pasteurization does not eliminate the need for established safe food-handling and cooking practices, but rather helps to reduce the dangers of primary and cross-contamination. Irradiation sterilization requires a radiation dose approximately 10 to 30 times greater than does pasteurization and is defined by its ability to achieve a minimum 12-log reduction in *Clostridium botulinum* spores, which is the standard of microbial reduction in commercial retort canning.[8]

The Status of Food Irradiation

A comprehensive historical review of food irradiation has been published by Josephson.[9] In 1958, Congress revisited the Food, Drug and Cosmetic Act of 1938 and added to it the Food Additives Amendment (FAA). The FAA classifies food irradiation as a food "additive," which is technically incorrect since no substance is physically added to the food. The classification has been defended on the basis that irradiation of food induces chemical change in the product; however, baking, broiling, frying, grilling, canning, microwaving, and freeze-drying all induce similar changes, but are classified as processes.

In the United States, irradiation is approved for the applications of insect disinfestation, shelf-life extension, pathogen and parasite control, and sprout inhibition.[4] Foods approved for irradiation include red meat, poultry, pork, fruits and vegetables, aromatic spices, seeds, herbs and seasonings, enzyme preparations, eggs, and wheat.[4] Pending or in review are applications for shellfish and processed meats.

Food Irradiation and Public Health

The World Health Organization (WHO) and the European Commission Scientific Committee for Food (EU-SCF) have assessed in detail the safety and benefits of food irradiation.[10,11] In addition, the science of food irradiation has been extensively reviewed by others.[12-17] As part of a Hazard and Critical Control Point plan, the standard industry approach to food safety, irradiation is an effective critical control point for most bacterial pathogens, including *Escherichia coli* O157:H7, salmonella, campylobacter, and listeria, as well as for parasites such as toxoplasma and trichinella.[16,18] The Centers for Disease Control and Prevention (CDC) estimates that if food irradiation were utilized for only 50 percent of meat and poultry consumed in the U.S., foodborne illnesses would be reduced annually by 900,000 and deaths by 352.[16] Given the probable number of unreported and undetected foodborne illnesses, this reduction is likely to be even greater.

Irradiation sterilization has been used on a limited basis by hospitals and long-term care facilities to provide immunocompromised patients with microbiologically safe meals that have a variety and quality superior to meals prepared using thermal sterilization alone.[12,8] Radiation sterilization has also been used by the National Aeronautics and Space Administration for astronauts' meals, and to provide shelf-stable foods to the military and outdoor enthusiasts.[19]

Irradiation facilitates the replacement of toxic and environmentally harmful chemical fumigants such as ethylene/propylene oxide and methyl bromide.[20] Another advantage of irradiation is that it can increase the shelf life of select foods, and it decreases losses from spoilage and pests. Loss reduction takes on special significance in the context of global distribution and storage of food to feed the world population.[21,22]

The additional consumer costs from volume irradiation processing are estimated to be less than five cents per pound for meat or poultry.[23]

Limitations of Irradiation

Irradiation of food is not a panacea. Bacterial spores are more resistant to irradiation than are vegetative cells and require doses significantly higher than those used in pasteurization.[12] In general, inactivation of viruses also requires doses beyond those used in phytosanitary treatment or irradiation pasteurization.[8,12] This is especially relevant for food items that will not be cooked or otherwise processed before consumption (e.g., fresh produce). Avoidance of human fecal contamination of such food items will remain the primary method of viral associated foodborne disease prevention. Toxins and prions are typically not eliminated by irradiation at standard commercial doses.[12] Irradiation of food does not prevent later contamination by consumers or food-service workers, although this is true of any processor-side intervention.

The impact of irradiation on the color, odor, and texture of foods is variable and correlates with dose, temperature, oxygen level, and packaging. Reported sensory tests of irradiated foods show differing results, with some reviews of irradiated products describing taste, color, or odor degradation and others finding insignificant or unnoticeable differences in sensory characteristics between irradiated and nonirradiated foods.[24,25,26] Recent improvements in food irradiation technologies and techniques are expected to reduce or eliminate the impact of the process on sensory quality.[13]Irradiation is not suitable for all foods. Some fruits, vegetables and dairy products experience degradation in shelf life and product quality following irradiation and thus are unlikely candidates for the process.

Arguments by Opponents of Food Irradiation

A brief review of three prominent arguments against food irradiation follows.

First, 2-Alkylcyclobutanones (2-ACBs), unique to irradiated foods, are oncogenic and mutagenic in animals and are harmful to people who consume irradiated food. This claim refers to European research findings from 2002.[27,28] The studies' authors did not investigate the safety of irradiated foods, but did report that formulations of chemically synthesized 2-ACBs, (in concentrations about 1000 times those found in irradiated foods) exhibited genotoxic and cytotoxic properties in vitro,[27] and that in rats treated with a known carcinogen, exposure to this level of 2-ACBs may be tumor-promoting.[28] The authors specifically cautioned against extrapolating their data to be an indictment of food irradiation.[27] The EU-SCF reviewed the 2-ACB research, and affirming its support of the WHO's assessment of irradiation safety, concluded that evidence of genotoxicity had not been established by standard methods and that the findings could not be considered relevant to the question of the safety of irradiated food products.[29]

Numerous animal and human feeding studies examining irradiated foods have, *de facto*, tested the safety of 2-ACBs, but have not found them toxic or oncogenic.[19,30] Additionally, in vitro "Ames" and *E. coli* tryptophan reverse mutation assays of 2-ACBs have shown no genotoxicity.[24,31] Given the available evidence, any claim suggesting that the studies on 2-ACBs are directly relevant to the safety of irradiated foods is lacking in scientific credibility.

Second, irradiation destroys the nutritional quality of food. The addition of any energy to food can break down its constituent nutrients and molecules. In general, macromolecules such as carbohydrates, proteins and fats are not significantly affected by irradiation.[32] Thiamine (vitamin B_1) is among the vitamins most sensitive to radiation, but food irradiation is not considered to pose a threat to dietary intake of thiamine. Both a review by the Food and Drug Administration (FDA)[32] and an independent Argentinean study[33] have concluded that irradiation poses no significant risk to any nutrient in the diet, a conclusion supported by the American Dietetic Association.[34]

Third, irradiation is a "quick fix," the technological solution to a policy problem. Food irradiation has been portrayed as an easy way for industry and government to cover up or ignore the sanitary state of meat- and poultry-processing facilities. Traditional safety measures have the primary role in ensuring the safety of our meat supply, but they will not eliminate *all* contamination, particularly in a slaughterhouse environment. For example, testing for *E. coli* O157:H7 in ground beef by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service in 2003 found only a 0.32 percent contamination level.[35] Because the United States produces about 8 billion pounds of ground beef annually, even this exceedingly low level of contamination means production of an estimated 25.6 million pounds of *E. coli* O157:H7 contaminated ground beef each year.[35] Irradiation cannot prevent primary contamination, but it can help to ensure that contaminated ground beef does not reach the marketplace.

Future Opportunities

Food irradiation is at a crossroads in the United States. Significant opportunities for large-scale implementation of food irradiation are emerging. For example, beginning in January of 2004, the USDA will offer irradiated ground beef as part of the National

School Lunch Program, which provides daily meals to approximately 27 million children nationwide. Furthermore, it is anticipated that the FDA will soon approve a pending request to authorize irradiation for use on cold-cuts and processed meats; this will be an important opportunity to reduce the risk of diseases such as listeriosis.

As irradiated foods become widely available, public demand and public health advocacy will determine if food irradiation grows beyond its current niche to have a measurable impact on food safety. In the 1930s and 1940s physicians and allied health professionals played an important role in the consumer acceptance of milk pasteurization. As health advocates, they have that role to play again in the adoption of food irradiation. We believe that physicians and health professionals should be prepared to knowledgably answer patients' questions regarding food irradiation; recommend irradiated foodstuffs, particularly for immunocompromised individuals, pregnant women, children, and the elderly; encourage endorsement of irradiated product use by local and state medical professional organizations; encourage grocers to stock irradiated foodstuffs; and support the use of irradiated beef in school lunch programs.

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Table 1 Selected Organizations That Support the Safety of Food Irradiation

United States Government Agencies

• Department of Agriculture

• Department of Health and Human Services

o Food and Drug Administration

o Centers for Disease Control and Prevention

United States Scientific and Health-Related Organizations

• American Academy of Pediatrics

• American Dietetic Association

• American Medical Association

• American Veterinary Medical Association

• Council for Agricultural Science and Technology

• Council of State and Territorial Epidemiologists

• Infectious Diseases Society of America

• National Association of State Departments of Agriculture

International Scientific and Health-Related Organizations

• Codex Alimentarius Commission

• Food and Agriculture Organization of the United Nations

• International Atomic Energy Agency

• Scientific Committee for Food of the European Union

• World Health Organization

Food Processing, Food Service, and Related Groups

- American Meat Institute
- Institute of Food Technologists
- Food Marketing Institute
- Grocery Manufacturers of America

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Food Irradiation

Foodborne disease leads to about 325,000 hospitalizations and 5,000 deaths each year in the United States. Food irradiation could sharply reduce the incidence of foodborne disease, but currently it is rarely used. This article examines the reasons for the slow growth in the use of food irradiation. Physicians can help educate consumers about the role of irradiation as a strategy to improve food safety, just as physicians helped consumers to understand the benefits of pasteurization.

For Immediate Release

CFC Logistics Irradiator Receives USDA Approval, Starts Irradiating Beef

Milford Twp, PA, February 19, 2004 - CFC Logistics of Milford Township (Quakertown), PA, a 150,000 square-foot cold storage warehouse and irradiator operation received USDA approval Feb. 13, marking an important milestone for the business.

The USDA approval now opens the doors for the meat industry to use CFC Logistics' irradiation services with confidence as an additional food-safety measure.

"We've been in contact with a lot of beef companies lately, and have been running samples for them, but now we are ready for full-fledged production with meat," says Jim Wood, President. He says the customers who have sampled the ground beef products that have been treated with CFC Logistics' gamma-based irradiation equipment have all said that products were "superior on both taste and quality" than meats that had been treated with other irradiation methods.

"This is good news for the industry, and good news for the customers," Wood says. "Gamma irradiation penetrates foods thoroughly and evenly, and our customers are telling us that the results are as good, if not better than the electron beam".

With the USDA approval complete, two of the many beef companies that were testing products at CFC Logistics have begun scheduling truckloads for irradiation. A third company that sells to the federal school lunch program will also be irradiating beef as soon as the government paperwork is complete.

Meat companies now have the benefit of using CFC Logistics facility for not only irradiation, but also for blast-freezing, storage and distribution as well. "The multiple uses of our cold-storage facility will make irradiation an attractive food-safety alternative for companies that may not have otherwise considered it," says Wood.

Currently, CFC Logistics is the only USDA-approved irradiator in the country operating within a cold storage facility.

Conveniently located just off the Quakertown interchange on the Northeast Extension, the facility provides superior access to the PA Turnpike, Interstates 78 and 80 with easy on/easy off access for truck drivers. It is within a 100-mile radius of major markets, cities, and the ports of Philadelphia, Wilmington, and New Jersey / New York.

Irradiation is a proven technology that destroys harmful bacteria in food, and is endorsed by the largest, most prominent scientific, medical and government organizations, such as the American Medical Association, the U.S. Department of Agriculture, the Centers for Disease Control and Prevention, the American Council on Diet and Health, and the World Health Organization. It is seen as an important public safety control to help prevent food contamination, that causes 76 million illnesses and 5,000 deaths in the U.S. each year. At least 60 of those deaths are from E. coli. The CDC says even if only 50 percent of the population chooses irradiated beef, it will still prevent nearly 900,000 cases of food-borne illnesses and 350 deaths each year.

CFC Logistics, Inc., is a subsidiary of the Clemens Family Corporation of Hatfield, PA, who owns Hatfield Quality Meats, Inc. of Hatfield, PA, Wild Bill Foods of Lancaster, PA, and Country View Family Farms, of Lancaster, PA. "We are pleased to help the food industry move toward a safer food supply", says Phil Clemens, Chairman and CEO of CFC.

The GENESIS Irradiator™ used by CFC Logistics was designed by GRAY*STAR, Inc. of Mount Arlington, NJ.

Contacts for CFC Logistics:

Jim Wood, President 215-529-1500; jwood@cfclogistics.com <mailto:jwood@cfclogistics.com>

Paul Moriarty, Director of Sales & Marketing 215-529-9522 pmoriarty@cfclogistics.com <mailto:pmoriarty@cfclogistics.com>

Sharon Turner, Irradiation Services Manager 215-529-9522; sturner@cfclogistics.com <mailto:sturner@cfclogistics.com>

Website: www.cfclogistics.com <http://www.cfclogistics.com>

Contacts for Gray*Star, Inc.:

Martin Stein, Chief Executive Officer: 973-398-3331; graystarnj@aol.com <mailto:graystarnj@aol.com>

For Immediate Release

Pennsylvania Irradiator is Now Fully Operational

Milford Twp, PA, January 13, 2004 - CFC Logistics of Milford Township (Quakertown), PA, a 150,000 square-foot cold storage warehouse, has officially kicked off the operation of its much-anticipated food irradiation unit with the commencement of its first ground-beef customer who began testing product samples on January 8.

With USDA-approval of this facility imminent, the CFC Logistics irradiator will be dedicated to meeting the needs of the Food Industry in the Northeast. Services provided will meet the requirements for maintaining the cold chain of all segments of the food industry including meat, poultry, fruits and vegetables, and spices. "Having an irradiator located within a cold storage/logistics operation provides a unique service opportunity for food processors and retailers who want to irradiate their food and perishable products," said Jim Wood, President of CFC Logistics, Inc. Currently, CFC Logistics is the only irradiator in the country operating within a cold storage facility.

The GENESIS Irradiator™, designed by GRAY*STAR, Inc. of Mount Arlington, NJ, provides the customer flexibility in terms of product mix, shape, fresh or frozen, and variety in packaging. Russell Stein, designer of the GENESIS Irradiator™, says "Customers can use their standard packaging up to 24" thick, there is no requirement to redesign the shape or size of the product to be used in our irradiator." CFC Logistics selected the GENESIS Irradiator™ for its versatility, cost-effectiveness, dependability, and ease of installation.

Conveniently located just off the Quakertown interchange on the Northeast Extension, the facility provides superior access to the PA Turnpike, Interstates 78 and 80 with easy on/easy off access for truck drivers. It is within a 100-mile radius of major markets, cities, and the ports of Philadelphia, Wilmington, and New Jersey / New York.

Irradiation is a proven technology that destroys harmful bacteria in food, and has been endorsed by many prominent scientific, medical and government organizations such as the US Department of Agriculture, the Center for Disease Control and Prevention, The American Council on Diet and Health, and the American Medical Association.

CFC Logistics, Inc., is a subsidiary of the Clemens Family Corporation of Hatfield, PA, who owns Hatfield Quality Meats, Inc. of Hatfield, PA, Wild Bill Foods of Lancaster, PA, and Country View Family Farms, of Lancaster, PA. "We are pleased to help the food industry move toward a safer food supply", says Phil Clemens, Chairman and CEO of CFC.

Contacts for CFC Logistics

Jim Wood, President 215-529-1500
Sharon Turner, Irradiation Services Manager 215-529-9522

Paul Moriarty, Director of Sales & Marketing 215-529-9522

Subj:	**GrayStar PR Email TEST**
Date:	12/9/03 4:59:40 PM Eastern Standard Time
From:	rich@siriusad.com
To:	GrayStarGenesis@aol.com
File:	**GRAYSTARGenesis.jpg** (181055 bytes) DL Time (24000 bps): < 2 minutes

Sent from the Internet (Details)

GRAY✦STAR

Mt. Arlington Corporate Center, 200 Valley Rd.
Suite 103, Mt. Arlington, NJ 07856

For Immediate Release
Contact: Russell Stein, GRAY*STAR, INC., 973-398-3331
GrayStarGenesis@aol.com

NATION'S FIRST GAMMA IRRADIATOR INSTALLED INSIDE COLD STORAGE FACILITY

PROVIDES FLEXIBILITY FOR THE FOOD INDUSTRY AND SAFTEY FOR CONSUMERS

DECEMBER 4, 2003 (Mount Arlington, NJ) – The Genesis IrradiatorTM, the first practical, self contained, gamma irradiator specifically designed to process food, has been installed and is operating in a cold storage facility north of Philadelphia in Milford Township, PA. The announcement was made by GRAY*STAR, Inc., the designer and manufacturer of the irradiator.

"Finally it's practical to provide safer food through irradiation," said Martin Stein, CEO of GRAY*STAR, Inc.

Unlike other irradiators used to process food which require massive structures for above ground shielding, the Genesis is a piece of food-processing equipment, which can be installed with minimal preparation into an existing processing or packaging plant. Its size, simplicity and ease of operation make the irradiation of food products convenient and cost effective. Instead of lifting the source out of the pool into a shielded chamber, the product is lowered into the pool adjacent to the source. To accomplish this, the product must obviously be kept dry, and a solution to the problem of lost efficiency that is normally associated with underwater irradiation, had to be found. GRAY*STAR scientists and engineers solved both of these problems, resulting in the inherently safe Genesis. Because the heavy above-ground shielding is not required, the Genesis is also far less expensive than competitive irradiators, and takes up far less space.

"Thanks to the efforts of SureBeam and Food Technology Services, irradiation has become a fully accepted method of eliminating harmful bacteria that can contaminate our foods and cause serious illness," said Russell Stein of GRAY*STAR, the designer of Genesis. "Before Genesis, food producers had to depend on a select few outside resources, often hundreds of miles away, to irradiate food. The cost to transport the food to and from those facilities could be prohibitive. Now, food companies can install this affordable unit in a processing plant or food storage facility and drastically reduce the cost per pound of providing safe product.

Genesis is capable of processing 200,000 lbs. of food per day and is fully modular in that additional units can be added to increase production. Food does not need to be repackaged because Genesis effectively irradiates thicknesses up to 24", another money saving feature. Perhaps the biggest benefit is the time it takes to build and install Genesis – just six months from purchase to being fully operational according to GRAY*STAR.

The components of the Genesis are engineered and fabricated for GRAY*STAR by CHL Systems of Souderton, PA, which has been providing high quality equipment to the food processing industry for over 45 years.

The first Genesis installation at CFC Logistics, Milford Township, PA, is a typical example of how this compact, easy-and-safe-to-operate irradiator better fits the business model of the food industry than its predecessors. The entire irradiator, which requires a footprint of just 1,600 sq. ft., is housed within CFC's cold storage facility. Here, perishables can be irradiated and stored, eliminating high transportation costs. Also, since the cost to install Genesis is a fraction of what it previously cost to build an irradiator, irradiation will make more sense for many food companies. CFC Logistics plans to market its irradiation services to food producers, making it the most convenient and cost effective choice for companies in the Northeast. Currently, the only other food irradiators in the country are located in the Midwest and South.

Food irradiation is endorsed by every major health organization in the World as an important step in alleviating suffering and in saving lives that are lost every year to food borne illnesses. For more information about the benefits of food irradiation, visit the web site of the Food Irradiation Processing Alliance at www.fipa.us.

"The successful licensing and completion of the first Genesis unit has elicited a great deal of enthusiastic interest from the food industry," said Martin Stein. "We anticipate that we will soon be installing many of these units here in the United States as well as abroad."

For information regarding CFC Logistics, visit www.cfclogistics.com.

For more information regarding CHL Systems, visit www.chlsystems.com.

For information regarding the Genesis Irradiator, visit www.graystarinc.com.

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Chile honors US expert for pre-clearance plan

Al Marulli, formerly of USDA-APHIS, was last year recognized by the Chilean government for his role in establishing Chile's fruit pre-clearance program

THE Chilean government last year honored US quarantine expert Albert Marulli for his outstanding contribution to the Chilean fruit industry, during celebrations commemorating 25 years of collaboration between the US Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS), Servicio Agricola Ganadero (SAG) and Asociacion de Exportadores de Chile (ASOEX).

Chile's president, Ricardo Lagos, led proceedings in which Marulli was officially recognized for his work on the Chilean fruit pre-clearance and inspection program – a scheme said to have helped boost the country's exports. Marulli, who was unable to attend the event, was credited with the success of the program and honored for "his vision, planning and its implementation".

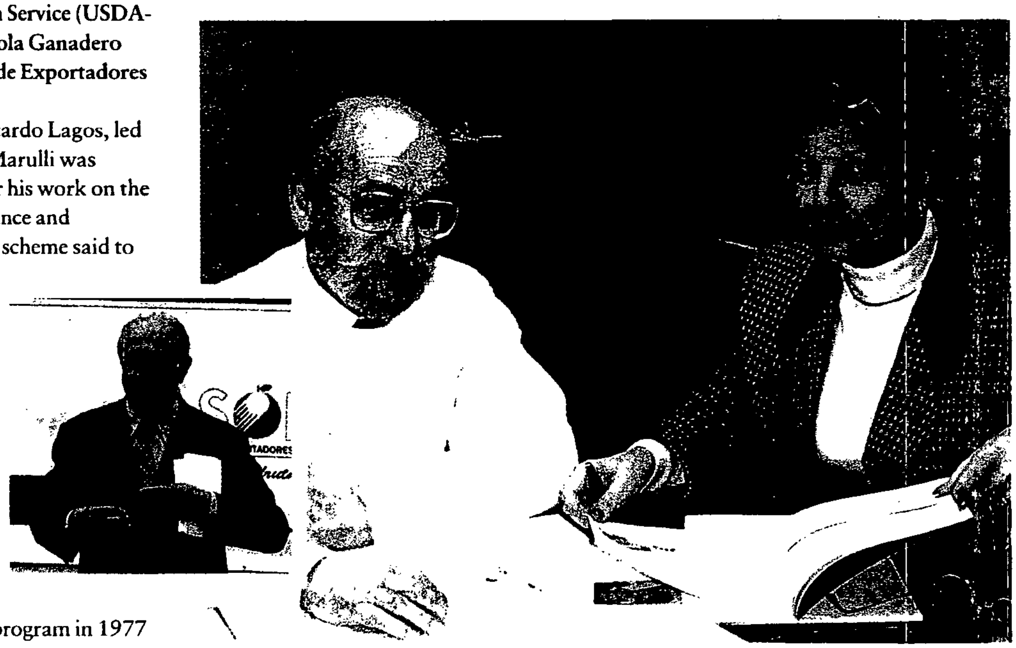
Marulli drafted the program in 1977 when working for USDA-APHIS, and instigated the tripartite coalition between SAG, USDA-APHIS and ASOEX soon after.

In a written statement read out at the ceremony, Marulli said: "I consider the work I did in Chile one of the most rewarding of my career. It was a job I enjoyed, and I found a country and people I came to respect and admire."

He added that the program developed slowly in the early years, but when the *Memorandum of Understanding* was finally signed in 1977 by APHIS, SAG and ASOEX, the necessary coalition was established.

"With this coalition, the participation of INTEC and the academic institutions in Chile, the program took on new momentum. It is evident that this team effort has served Chile well, over the last 25 years," he said.

"My friends and key collaborators, Señor Jamie de la Sotta and Señor Orlando Morales must be commended for their full, dedicated and invaluable participation in advancing the program...[and] I want to express my sincere gratitude to the people who carried out the inspectional and technical activities of SAG. On behalf of their colleagues, I want to acknowledge Señor Jamie Bahamondes and Señora Ingeborg Rosenbaum for their guidance, performance and dedication."



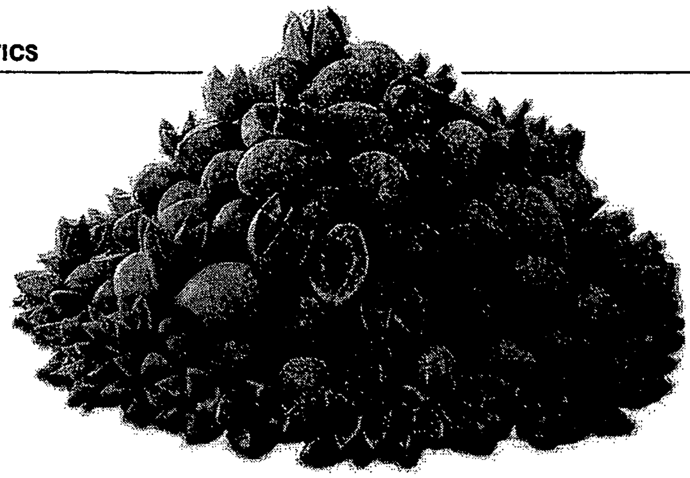
Albert Marulli (above) continues to work on quarantine issues with Barbara Hunter at his company, Agricultural Trade Services. *Inset:* his excellency Ricardo Lagos

Barbara Hunter of US firm Western Fumigation, who accepted the award on Marulli's behalf, said: "During my 20 years of friendship with Albert, I learned that in many ways Albert is a paradox, a contradiction. He will fight fearlessly and fight hard for what he believes in.

"He is determined and a powerful force to be reckoned with when principles are at stake," she added. "At the same time, he is a shy and unassuming man, who has never sought personal recognition."

Marulli acted in several capacities during his 30-year career with USDA-APHIS and served in many countries prior to his assignment in Chile. On leaving APHIS in 1983, Marulli set up a consulting business, Agricultural Trade Services, which still responds to US quarantine issues.

Over 1,000 dignitaries and industry representatives from Chile and the US attended the November event in Santiago last year. ★



Ridding exotic fruits of bugs

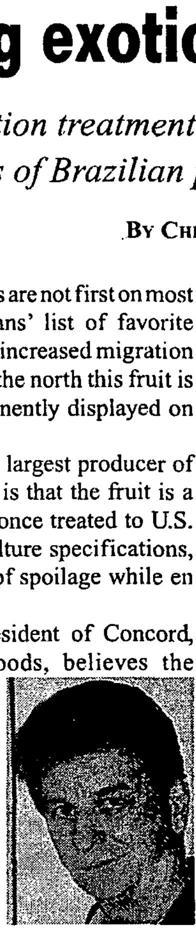
Irradiation treatment promises to boost U.S. imports of Brazilian papayas and mangoes.

BY CHRIS GILLIS

Brazilian papayas are not first on most North Americans' list of favorite fruits, but with increased migration of Latin Americans to the north this fruit is becoming more prominently displayed on grocer shelves.

Brazil is the world's largest producer of papayas. The problem is that the fruit is a magnet for pests and, once treated to U.S. Department of Agriculture specifications, often risks high rates of spoilage while en route to U.S. markets.

George Karski, president of Concord, N.H.-based SecureFoods, believes the answer to winning a place for Brazilian papayas in U.S. fruit bowls, and improving its transport overseas, is to use irradiation treatment technology. His company, a subsidiary of gold mining and energy investment firm Brazilian Resources, is prepared to spend millions of dollars to build and operate irradiation equipment for Brazil's papaya export industry.



Karski

Brazil's papayas are traditionally treated for fruit flies with hot water dips. The treatments, while generally successful, degrade the fruit's potential shelf life. Cheaper ocean transport is out of the picture for most Brazilian papaya exporters, who must use costly air transport to ship to U.S. markets.

According to Karski, Brazilian papayas that do arrive in the United States in sellable condition still get shortchanged. "The fruit is picked long before it ripens and tastes like cardboard," he said in a recent interview.

Irradiation treatment facilities placed close to growing areas will allow Brazilian papaya farmers to pick the fruit closer to its peak of taste, Karski said. Irradiation kills harmful bacteria and embedded insects, without changing the overall quality of the fruit.

More importantly, it slows ripening to allow Brazil's papaya exporters to take advantage of ocean transport. "The only loser from irradiation treatments will be the airline industry," Karski said.

The average cost to fly a 10-pound carton of papayas from Brazil to the United States is about $9, compared to $1 per case for ocean transport. The fruit is generally sold to wholesalers who command a 10 to 15 percent commission from retailers. If ocean transport is used, the fruit could be sold at U.S. retail for about 90 cents per papaya, compared to more than $1.50 with air transport, Karski explained.

Ultimately, SecureFoods will use irradiation to treat a variety of Brazilian fruits, such as mangoes, for export to North America and Europe. It's estimated that Brazil ships abroad more than $160 million in tropical fruits a year.

The Brazilian agricultural authorities support SecureFoods' irradiation treatment initiative, but the program still requires bilateral approval from USDA's Animal and Plant Health Inspection Service, which Karski believes will happen soon.

Once SecureFoods gets its USDA approval, it will install four food irradiators in Bahia in Northeast Brazil. The region's papaya production outstrips its domestic consumption. "Fruit is often discarded, or left rotting in the fields," Karski said.

SecureFoods' first irradiator will be located in Eunapolis, Bahia, near the port of Ilheus. The second unit will be installed at Salvador, a large port and the capital of Bahia. Fortaleza, Ceara, and Recife, Pernambuco, both of which are large papaya export areas, will be the sites for the two other units, Karski said.

Irradiation technologies have been used for more than 40 years to sterilize medical, personal hygiene products and food packaging. In recent years, the meat industry has used irradiation to kill harmful bacteria, such as E. coli, salmonella, listeria, campylobacter and vibrio, in beef and poultry. Exposure to these bacteria contributes to 76 million food borne illness and about 5,000 deaths a year in the United States alone.

About 40 countries have approved irradiation treatments for about 40 food products. The International Consultative Group on Irradiation estimates that irradiation is used to treat about a billion pounds of food products and ingredients a year. In the United States, about 80 million pounds of spices are irradiated annually.

Numerous health organizations and government agencies, such as the American Medical Association, American Dietetic Association, U.S. Center for Disease Control and Prevention, U.S. Food and Drug Administration, and World Health Organization, approve irradiation as a safe way to treat food products.

In 2002, USDA approved irradiation treatment for certain imported fruits and vegetables against 11 types of fruit flies and the mango seed weevil. However, the technology's use for this purpose has been minimal. USDA allows irradiation treat-

Produce pests

Fruit flies and seed weevils in imported fruits and vegetables approved by USDA for irradiation treatments

1.) Oriental fruit fly
2.) Mediterranean fruit fly
3.) Melon fly
4.) South American fruit fly
5.) Caribbean fruit fly
6.) Mexican fruit fly
7.) West Indian fruit fly
8.) Sapote fruit fly
9.) Queensland fruit fly
10.) Bactrocera jarvisi (no common name)
11.) Malaysian fruit fly
12.) Mango seed weevil
13.) Sweet potato stem borer
14.) Sweet potato vine borer

USDA's Animal and Plant Health Inspection Service will not accept irradiated commodities as a quarantine treatment for other countries until framework equivalency agreements are signed between the agency and its overseas counterparts.

ments for interstate movements of certain exotic fruits and sweet potatoes from Hawaii to the U.S. mainland.

Interest in the technology has increased in recent years with common-use fumigations and chemical treatments coming under increasing fire for their negative environmental and public health effects.

Methyl bromide is one of the most widely used fumigants for phytosanitary purposes in the United States and around the world. The fumigant, unlike others, penetrates produce completely without altering its appearance or taste. However, some scientists and environmental groups have pegged methyl bromide a major contributor to the earth's ozone depletion, especially when it's used for large-scale soil treatments.

In 1992, the 183 parties to the Montreal Protocol, including the United States, added methyl bromide to the list of ozone-depleting substances, and production was frozen in 1995 to 1991 levels. When the parties met again in 1995, they agreed to completely phase out the gas among industrial countries by 2010.

In 1997, the Montreal Protocol accelerated methyl bromide's phase-out for industrial countries to 2005. Starting in 1999, the use of the gas was reduced by 25 percent and by 50 percent in 2001. By January 2003, methyl bromide's use was cut by 70 percent. Methyl bromide use in developing countries will end by 2015.

For quarantine purposes, the United States and other industrialized countries will allow approved agricultural products shippers to continue using methyl bromide.

Even for those shippers allowed to continue using methyl bromide, the cost of the treatments is expected to increase. Before 1999, methyl bromide treatments for cherry exports were generally $1.25 per pound. Today, methyl bromide fumigations exceed $5 per pound for this commodity.

Shippers and treatment providers are considering alternative treatments to methyl bromide. USDA, which has spent more than $146 million in research and outreach related to the development of treatment alternatives, has become a proponent of irradiation technology.

"To me it provides a much safer environment than methyl bromide and other chemical treatments," said Inder "Paul" Gadh, import specialist with USDA's APHIS. "This technology has a lot of potential for use not just in the United States but in many countries."

From an operational perspective, it will be difficult for irradiation to completely replace methyl bromide.

"Irradiation is not a very good alternative for many methyl bromide fumigators," said Al Marulli, a former USDA official and proprietor of Agricultural Trade Services, based in Chicopee, Mass. "Not to say it can't be done, but they will have to figure out how to make money from it."

Fumigators have the benefit of mobility, whereas irradiation units are stationary and are most cost effective when they're located close to a constant flowing product source, which is the case in meat and produce packinghouses, Marulli said.

There are three types of irradiation technologies used for phytosanitary purposes: electron beams, X-rays and gamma rays. While each technology operates a little differently, the amount of radiation used is minimal.

There are four major builders of irradiation equipment: Gray*Star, MDS Nordion, Reviss Services and IBA. SureBeam Corp., another manufacturer, filed for bankruptcy earlier this year.

Irradiation units are generally sold to companies involved in product treatment activities. Belgium-based IBA's Guardion subsidiary is heavily involved in the treatment of spices. Steris Corp. operates 16 large irradiators around the country for sterilizing medical devices. Food Tech Services in Florida uses a Nordion unit to treat meat products. Earlier this year, CFC Logistics, a division of the Clemens Family Corp., installed a Gray*Star unit in its 150,000-square-foot cold storage facility to irradiate meat products.

After much evaluation, FoodSecure decided to pick Gray*Star units for its Brazilian venture. Unlike X-ray and electron beam technologies, which require enormous amounts of electricity and aboveground shielding, Gray*Star's Cobalt-60 Genesis irradiator is compactly built below floor level. The units, which have an operational footprint of about 1,600 square feet, are specifically designed to treat food, said Martin H. Stein, Gray*Star's chief executive officer.

Electron beams, while good for some sterilization and manufacturing processes, can usually penetrate produce no more than one inch. Gray*Star's Genesis machines use gamma rays to penetrate food products and take nine minutes from start to finish to treat a ton of product, Stein said.

Gray*Star's Genesis units cost about $2 million apiece and, if all the government permits are together, can be installed in less than six weeks, Stein said.

A big problem with implementing irradiation facilities is the political obstacle related to public fear of radioactivity. "Irradiation comes with a lot of baggage," he said.

The Food Irradiation Processing Alliance attempts to eliminate

Irradiating Hawaiian sweet potatoes

WASHINGTON

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service wants Hawaiian sweet potato growers to consider using irradiation treatments for their U.S. mainland-bound shipments.

The agency believes irradiation is a safe and effective treatment against sweet potato pests. Hawaiian sweet potatoes are generally treated with methyl bromide fumigation.

USDA rules require sweet potatoes grown in Hawaii, Puerto Rico and the U.S. Virgin Islands to be treated against stem and vine borers before they're transported to the U.S. mainland.

Since 1996, USDA has become increasingly open to the use of irradiation treatments for phytosanitary purposes and as a replacement to methyl bromide fumigation.

Unlike Puerto Rico and the U.S. Virgin Islands, Hawaii's sweet potato producers have access to an irradiator at Honolulu, which is operated by Hawaiian Pride.

Sweet potatoes are grown on the islands of Hawaii, Kauai, Maui and Oahu. Shipments are consolidated at the Port of Hilo, and then transported by barge to Honolulu at a cost of 2 to 3 cents per pound. A pallet of sweet potatoes weighs about 1,500 pounds, so the charge is about $35 per pallet for non-chilled shipment. Trucking and handling charges to move sweet potatoes from the pier to the Honolulu methyl bromide fumigation site and back to the pier or airport costs about $34 per pallet.

According to the USDA, the per-unit cost of methyl bromide fumigation is about $610 for one to six pallets, with some volume discounts. The U.S. phase-out of methyl bromide fumigation for purposes other then quarantine will increase this treatment's cost four-fold to at least $4.50 per pound by 2005.

It costs about 15 cents per pound to treat produce by irradiation, but the cost to treat one to two pallets of sweet potatoes is cheaper than methyl bromide fumigation because of volume discounts and the elimination of certain transportation costs, USDA said. USDA also has on-site inspectors to oversee the irradiation treatment process.

Hawaii began to use its irradiator in August 2000, and treats 500 to 1,000 boxes of papayas a day, four times a week.

Hawaiian farmers are encouraged to grow other crops to replace the state's falling sugar cane production. Sweet potatoes are grown year around in Hawaii. About 50,000 to 60,000 pounds a week are shipped from the state.

concerns about irradiation's use to treat meats, fruits and vegetables.

"There is no process as flexible, as thorough and as simple as irradiation for reducing the microbial contamination on food," the alliance said. "High pressure processing and other emerging technologies may eventually have some use, but none are as easily implemented or as universally applicable as irradiation."

The alliance defends the safety record of irradiation. "Many hundreds of published research studies tried to identify problems from eating irradiated foods, but failed to disclose any long-term health risks," the alliance said. Meats treated by irradiation are labeled for consumer awareness.

Yet, the industry still fights to defend its public image. Anti-irradiation groups, such as Public Citizen, Clean Water Action Alliance, Community Nutrition Institute, Government Accountability Project, Institute for Agriculture and Trade Policy and the Organic Consumers Association, claim these treatments substantially reduce key vitamins in food.

Stein said it also doesn't help the food irradiation industry that SureBeam has gone bust. With the exception of a machine operated by Hawaiian Pride, SureBeam shut down its electron beam units in Sioux City, S.D.; Chicago and San Diego, Calif., leaving many meat producers and retailers scrambling to find other irradiation treatment sources. SureBeam management blamed the company's collapse on lack of sufficient market, but soon after its bankruptcy filing accounting irregularities became evident.

"SureBeam's actions hurt our industry very badly," Stein said. "Every once in a while this industry gets raided by companies that make claims they can't conceivably meet."

Another lingering problem is the drawn-out regulatory process to approve irradiation treatments for imported foods. USDA's APHIS does not accept irradiated commodities as a quarantine treatment for foreign countries until a "framework equivalency agreement" is signed between the agency and the overseas plant protection agency.

Recent illnesses linked to bacteria on imported fruits and vegetables have left many people concerned about the effectiveness of currently prescribed pre-shipment treatments.

A 1999 salmonella outbreak in the United States was linked to Brazilian mangoes, which according to import records were treated by hot water dip to kill Mediterranean fruit flies. The U.S. Center for Disease Control and Prevention (CDC) traced the shipment back to a single farm in Brazil. Investigators found that the dip tanks on the farm were "unclosed, and toads, birds, and droppings of bird feces were noted in or near the tanks." CDC also found that dipping mangoes too quickly between hot and cool water tanks causes the fruit to contract, encouraging pathogens to enter through the skin.

The USDA responded to this case by recommending that mango exporters adequately filter and chlorinate their dip tank water. The agency also asked these exporters to wait 30 minutes between the hot and cool water dips.

Some industry experts believe hot water dip treatments should be replaced by new technology such as irradiation. "Hot water treatment has proven to be untrustworthy," Karski said.

In December, the Mexican Association of Mango Exporters and Phytosan S.A. de C.V. said it plans to build an irradiation facility near the port city of Mazatian. Construction of the facility is scheduled to begin in May and should be fully operational for the mango season, starting in March 2005. The association plans to build another irradiation unit at the Reynosa, Tamaullpas/McAllen, Texas border crossing. The association believes hot water dipping in Mexico could be eliminated within the next seven years.

The Philippines, another mango exporter, reported plans last year to install irradiation units to treat for fruit flies and increase its world market share. ■

J. PETER CLARK
Contributing Editor
Consultant to the Process Industries
Oak Park, Ill.

Modular Unit Delivers Irradiation Pasteurization

An irradiation facility capable of pasteurizing up to 60 million lb of fresh meat and poultry per year is being installed at CFC Logistics in Quakertown, Pa. Martin Stein (phone 973-398-3331), President & CEO of Gray*Star, Inc., Mt. Arlington, N.J., said that its Genesis system is a revolutionary Category III irradiation facility designed to be smaller, less expensive, and easier to install and license than the current large facilities used for medical devices and some foods.

Irradiation is a long-studied and reliable technique for treating a variety of foods with various effects. At low doses, below 1 kiloGray (kGy), potatoes are inhibited from sprouting, insects in grain are kept from reproducing, fruit is delayed in ripening, and mold on fruit is destroyed. At larger doses, 1–10 kGy, pathogens on poultry or meat are destroyed. And at the highest doses allowed, 10 kGy and above, spices and dehydrated vegetables are sterilized.

Three sources of radiation are approved: cobalt-60, electron beams, and x-rays. Cesium-137 is another potential source but is currently used for research, not production. Radioactive isotopes (cobalt-60 and cesium-137) and x-rays produce energy in the form of photons, while electron beams generate a beam of electrons. X-rays are created by first generating an electron beam and then directing it at a metal target from which penetrating photons are produced. The gamma rays from isotopes and the beams from an x-ray have different energies, but function the same way.

Radiation doses are measured ultimately by sensitive calorimetry, i.e., measuring the temperature rise due to exposure for a given time. A Gray is defined as 1 Joule/kg, and 1 kGy is about 0.4 BTU/lb. At the typical doses used for food pasteurization, the temperature rise is about 1 degree. In practice, doses are measured by specially treated polymers which undergo a color change in proportion to the dose received and which trace their calibration back to calorimetry.

> [The] irradiation facility [is] designed to be smaller, less expensive, and easier to install and license than the current large facilities used for medical devices and some foods.

Early research on irradiation of foods focused on sterilization for such applications as feeding astronauts in space and the military, but sterilizing doses can cause off-flavors in some foods. The process is still used for these special applications, but the large, civilian applications are for foods that are refrigerated or frozen and are pasteurized with lower doses than are required for shelf-stability.

The categories of irradiators refer to how the isotope source is stored and shielded. Category I is for small sources used in research. Category II uses air storage and air irradiation and is not used for food. Category III uses water shielding and irradiates under water. Category IV stores a source under water but moves it into air to expose a target. Typically, when a source is in air, it must have concrete shielding to protect surroundings from the radiation.

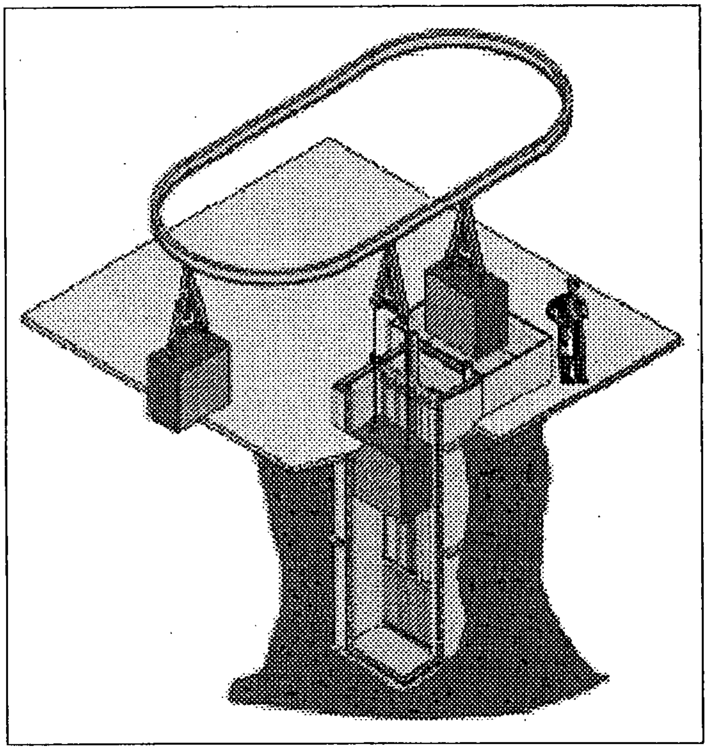
Because of the potential hazard to workers, special training is required for using any radiation device, whether it be for medical use, as in treating cancer, irradiating medical devices, or irradiating food.

Stein says that Genesis, with its scheme of keeping the source under 20 ft of water, requires less shielding and is less complex. Products to be treated are loaded automatically into "bells" which use compressed air to displace water and are lowered through the water pool to a position next to the source. The source is also in air under the water, separated by a thin steel panel which does not reduce the amount of radiation.

The Genesis system occupies only 1,200 ft^2 and can be built in about six months for about $1.25 million. Another $1.5 million is required for the initial load of cobalt-60. An owner of a Genesis unit obtains the source from firms that specialize in that business, such as MDS Nordion, a Canadian firm that specializes in technologies for nuclear medicine and irradiation, or Reviss, a British firm. A significant operating cost of isotope irradiation is replacement of the cobalt-60, which decays at the rate of about 1% per month. To compensate for the decay, some fresh sources are typically added every year. Eventually, depleted sources are returned to the supplier and new ones installed.

The shielding water in irradiators must be kept very clean to avoid any corrosion of critical components and to enhance visibility, as operations such as replacing sources must be conducted remotely through the water.

Food Technology Services, Inc., Mul-



Gray•Star Genesis Irradiator™ is capable of pasteurizing up to 60 million lb of fresh meat and poultry per year.

berry, Fla., was the first commercial food irradiator and has been treating fruits and vegetables for a number of years, according to Richard Hunter (phone 863-425-0039), President & CEO. The firm was founded in anticipation of the loss of methyl bromide as a disinfestation agent for fruits. This still has not occurred, but the firm has kept busy irradiating fresh and frozen fruits, vegetables, and meats. A petition to allow irradiation of ready-to-eat foods is pending before the Food and Drug Administration. The company uses a cobalt-60 irradiator provided by MDS Nordion, Ottawa, Ontario, Canada.

MDS Nordion has provided equipment and isotopes for more than 50 years, according to Carolin Vandenberg, Director of Marketing, and Joseph Borsa (phone 613-592-2790), Senior Product Manager. The company has built more than 100 facilities around the world, mostly for medical sterilization applications. The cobalt-60 sources are manufactured by exposing cobalt-59 rods in a nuclear reactor, where some of the atoms acquire an extra neutron to become the radioactive element cobalt-60. The cobalt-60 is then doubly encapsulated in stainless steel.

MDS Nordion also generates other isotopes for diagnostic and treatment applications, some of which are so short-lived that they are made to order and delivered by courier. The company operates two reactors in cooperation with the Canadian government for diagnostic and treatment isotopes. Cobalt-60 is produced in power reactors, where the cobalt-59 serves to absorb neutrons while producing the valuable cobalt-60.

The company offers the Centurion irradiator, which uses Cobalt-60 and is designed for food processing, and the Palletron, which uses x-rays for full pallets of food. Vandenberg and Borsa pointed out that there are advantages and disadvantages to each source of radiation. Gamma rays are emitted in all directions and are generally limited to targets about 2 ft thick. This means that some energy can be wasted, depending on the design and the density of the targets. Typically, pallets of food in cartons are reconfigured automatically before passing through any irradiator, to assure uniform exposure without overexposure of the outer surface.

Gamma rays can penetrate any product, but are affected by product density. They penetrate farther than do electron beams and about the same as x-rays. X-rays can be focused because they are generated in a beam, so while there is some energy inefficiency, typical pallets can be treated without reconfiguration. Electron beams have low penetration depth and so can only be used for thin targets, no more than about 3.6 in thick, exposed from two sides. Typical electron-beam treatments are for single layers of packaged hamburger patties or for packaging material.

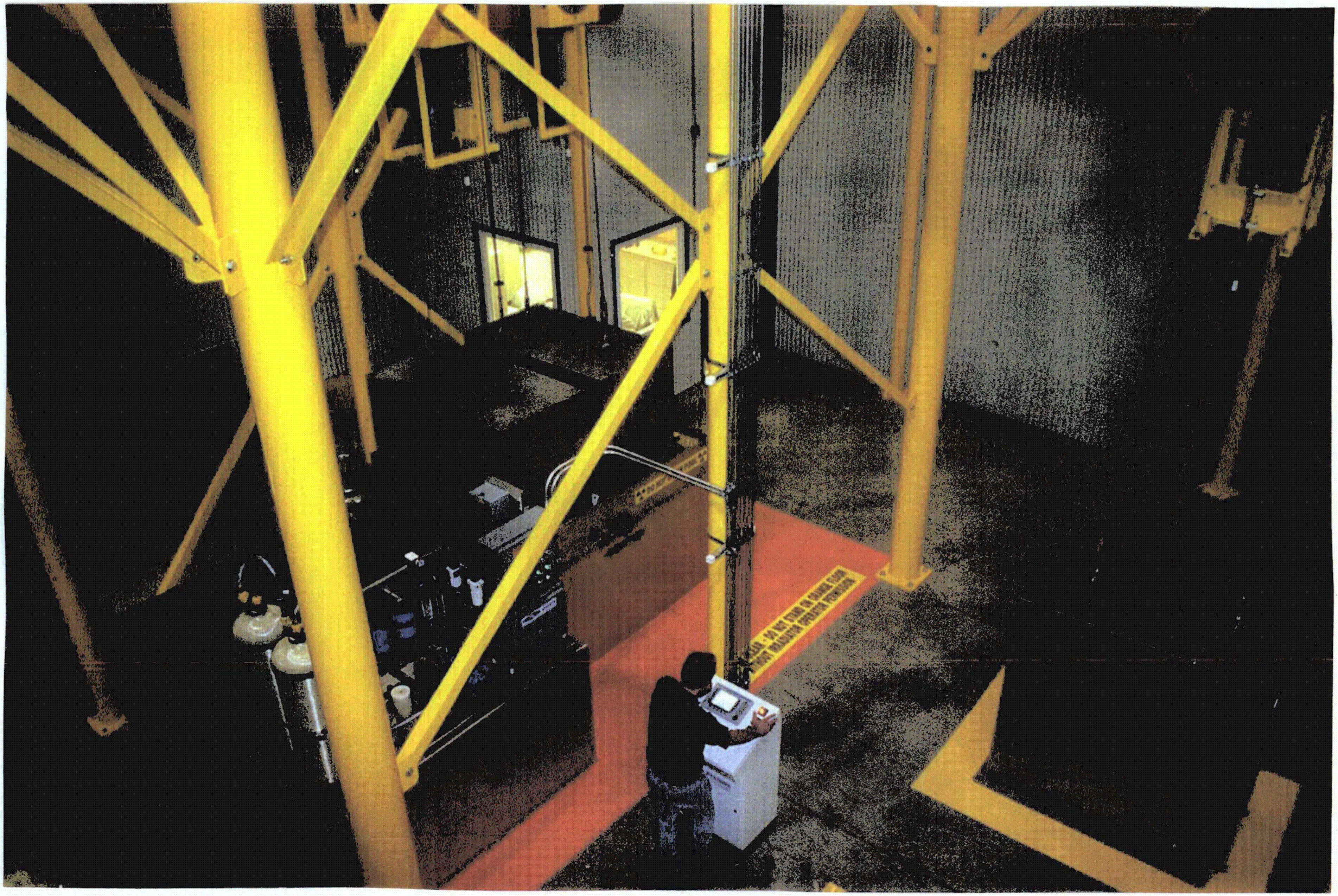
Both electron beams and x-rays have the advantage of being turned on and off by a switch, if necessary, according to Mark Stephenson (phone 858-795-6300), Vice President of Public Relations for SureBeam, Inc. of San Diego, Calif. SureBeam was spun off from Titan Corp., a diversified company, to commercialize its electron-beam and x-ray technology for food irradiation. SureBeam's approach is to build and operate service centers treating foods for supermarket chains and processors.

Packaged ground beef is a typical application, but the company also expects to treat poultry, fruits, and vegetables later this year. Electron beams are best with regularly shaped targets, while x-rays are better with thicker and irregular targets. SureBeam has service centers in Los Angeles, Chicago, and Sioux City and a research unit at Texas A&M University. An x-ray machine in Hawaii is used to treat papaya to prevent transmission of plant disease vectors to the mainland.

The suppliers of food irradiation equipment and services compete with one another, though costs of treatment are roughly equal, depending on utilization, energy costs (for those driven by electricity), and other costs. Most also cooperate through the Food Irradiation Processing Alliance (FIPA) based in Washington, D.C., to educate regulators, the public, and the industry.

All foods pasteurized by irradiation carry the radura, an international symbol alerting the consumer that the food has been treated by irradiation. There has always been concern, heightened by the positions of some activists, that the public would resist buying irradiated foods. In fact, such foods have been successful when offered in the market. Efforts to generate protests and boycotts have failed, even in the home territory of some of the organizations opposed to irradiation.

Irradiation is safe for the users and consumers and is a valuable tool in the collection of techniques used to offer safe and nutritious food to the market. All irradiators operate under their own Hazard Analysis and Critical Control Point plan, in which dose, exposure time, and temperature are controlled. Given the demonstrated hazards of emerging pathogens such as *Listeria*, *Escherichia coli*, and *Salmonella* and the ability of irradiation to eliminate them, it is likely that the radura will become a trusted symbol of safety on many packaged foods. ●



Genesis™

by GRAY ✦ STAR