TECHNICAL ASPECTS OF COMMERCIAL-SCALE OYSTER IRRADIATION

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What is Irradiation?

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- Irradiation means exposing something to radiation.
- Typically gamma rays from Cobalt 60 sources or X-rays or electron beams from generating machines.
- Energy from the rays kills living organisms by breaking chemical bonds in DNA.
- Safe, reliable process that is used to sterilize over 50% of single-use medical products.
- Cannot cause items to become radioactive just as a dental x-ray cannot make your teeth radioactive

Attributes of Gamma Irradiation

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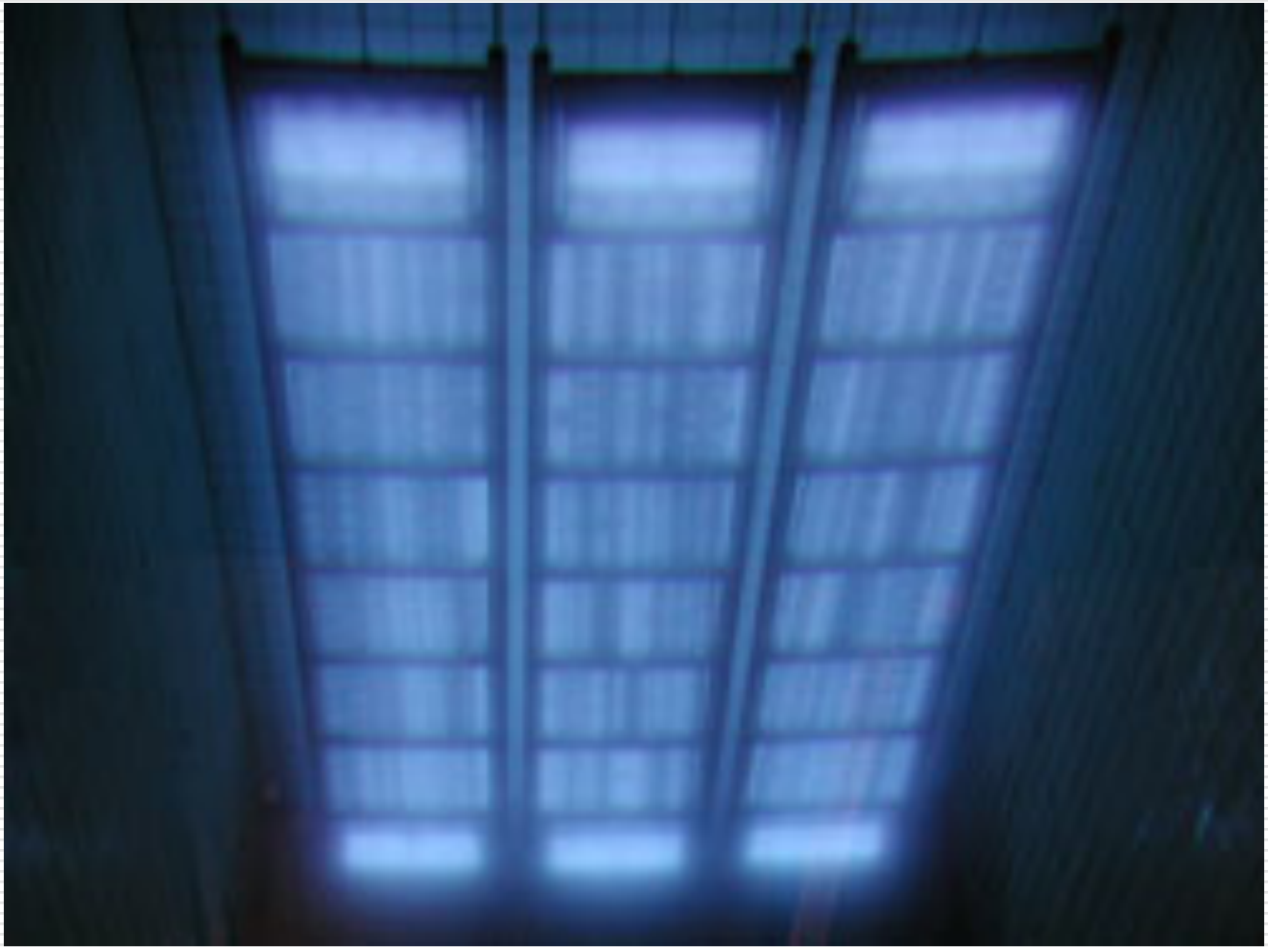
Energy is contained in sealed sources of Cobalt 60 that emit gamma rays.



Attributes of Gamma Irradiation

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Gamma Rays penetrate several feet of product

At a known source strength, time is only process variable.

Cold process – at low doses for food does not raise product temperature.

Product travels through process in carrier or totes and dwells at stations in radiation cell.

Length of time at each station controls the dose and is termed cycle time.

Carriers are typically full or half pallet and can be loaded via fork lift. Totes are smaller and generally hand-loaded.

Wet Pool Gamma Irradiator

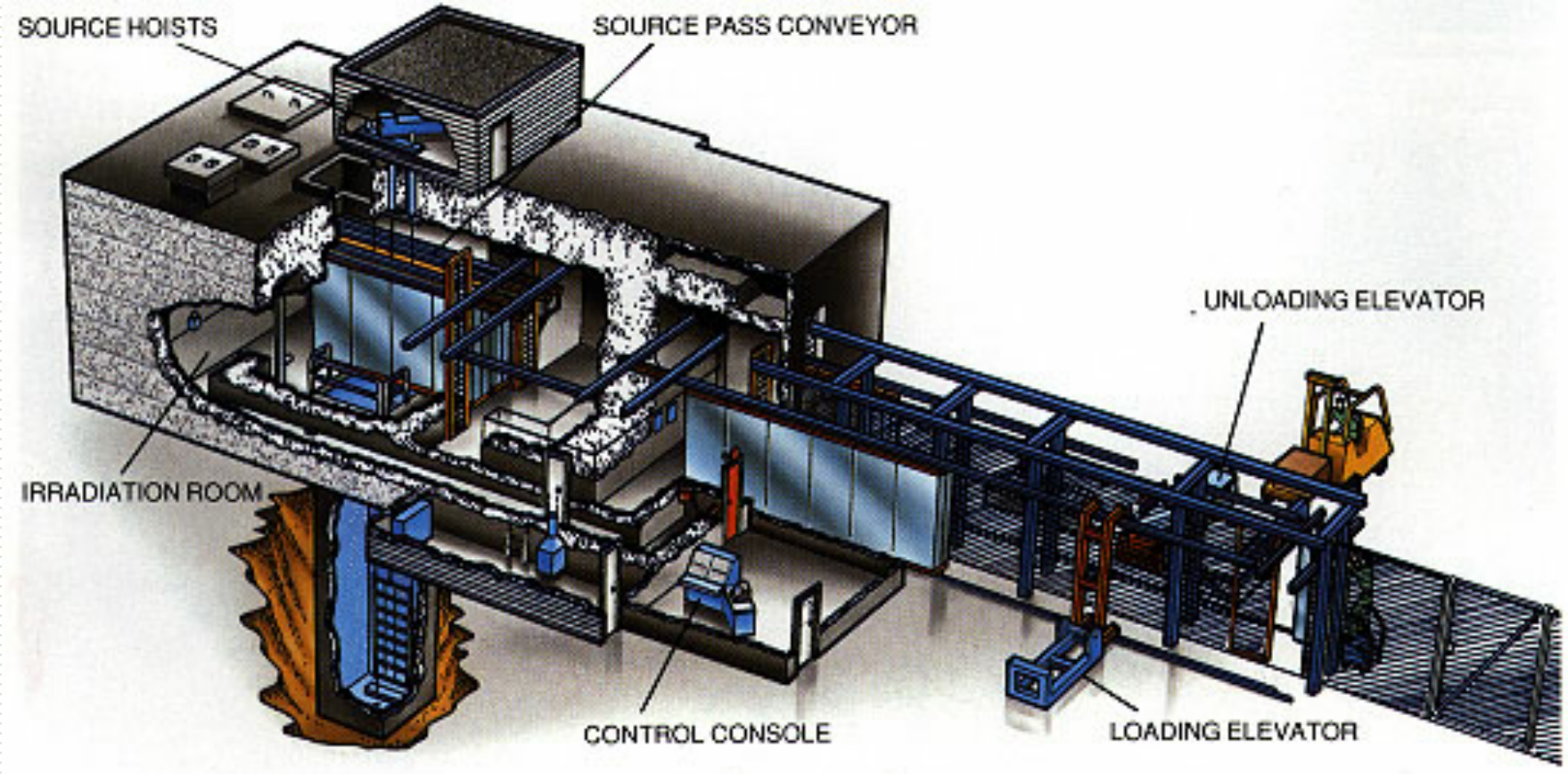
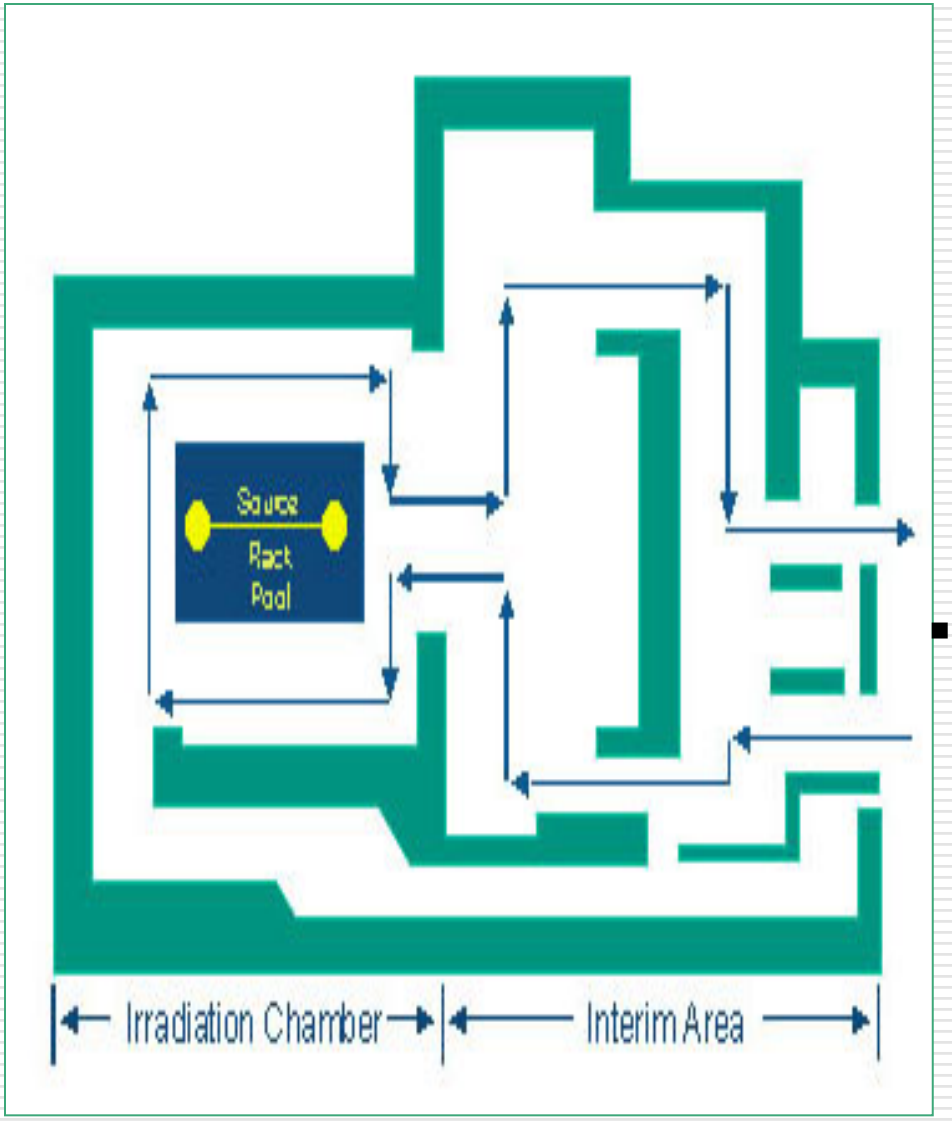


Figure 1: JS-8900 Unit Carrier Irradiator

Product Path Through Irradiator

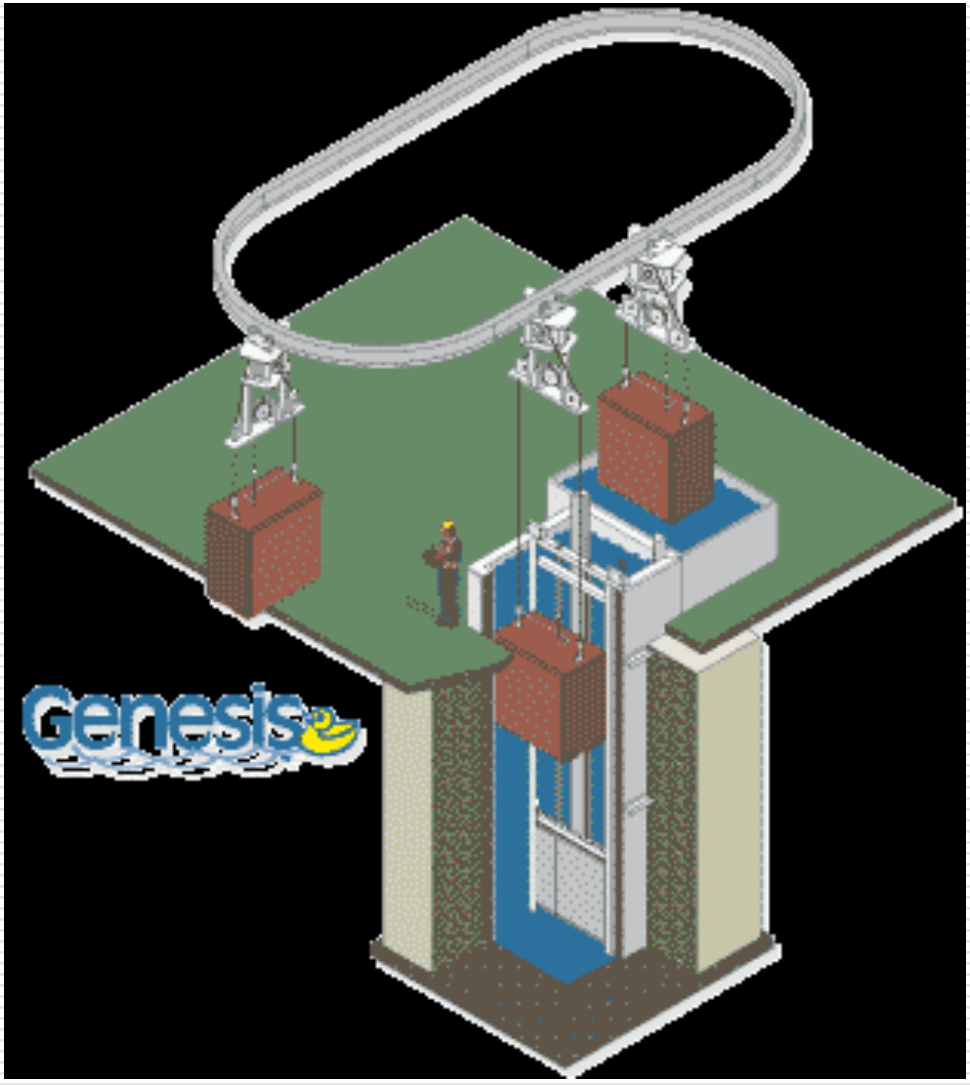


Pallet Carrier

Loading a Pallet Carrier

Loading a Tote

Underwater Gamma Irradiator



Gamma Facility Interior

Current Oyster Irradiators

FTSI recently sold to Sterigenics which has a significant presence in food irradiation. Sterigenics is evaluating the product mix and other factors before making a decision on whether to continue to offer oyster irradiation at the Mulberry facility.

Gateway American has opened a gamma facility in Gulfport, MS and is processing oysters. I do not have information on their pricing but they can be reached at (228) 701-0360 or visit http://www.gatewayamerica.net/

Irradiation and Vv

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Vv has a very low d-value (dose to reduce by 1-log) as compared to other bacterial food-borne pathogens.

Pathogen	1-log reduction dose (kGray)	5-log reduction dose (kGray)
Campylobacter	0.20	1.00
Toxoplasma cysts	0.25	1.25
E. coli 0157	0.30	1.50
Listeria	0.45	2.25
Salmonella	0.70	3.50
Vibrio vulnificus	0.015	0.75

Irradiation dose to decrease selected pathogens at 35º F by 1 decimal log (90%) and 5 decimal logs.

FDA Regulation of Oyster Irradiation

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- Food irradiation is classified as a food additive due to U.S. law passed in 1950s. Despite fact nothing is added, FDA wanted to require the strictest approval process
- Classes of food, dose and purpose must specifically be approved by FDA.
- Process begins with a petition demonstrating safety and efficacy of irradiation that is evaluated by FDA
- FDA approved molluscan shellfish for irradiation in August, 2005 with maximum dose of 5.5 kGy

FDA Regulation of Oyster Irradiation

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Specific PHP's must be validated and approved. FDA and DACS approved in December 2008

Based on review of the University of Florida's validation study, FDA concurs with approval by the Florida Department of Agriculture and Consumer Services for processors using this irradiation treatment to reduce levels of *Vv* to non-detectable to label oysters with NSSP safety added language. Recognizing that the PHP validation study submitted is to be used by multiple processors, it is understood that oysters intended for irradiation shall be packed in boxes and the boxes oriented on pallets and the pallets oriented within product irradiation carriers consistent with the packing and orientation upon which this process was validated.

Thank you for your continuing efforts to work with the shellfish industry to develop, validate and implement PHPs for reducing the level of *Vibrios* in molluscan shellfish. FDA looks forward to its continued working relationship with the Florida Department of Agriculture and Consumer Services and the Florida oyster industry.

Sincerely yours,

Paul DiStefano
US Food and Drug Administration
Center for Food Safety
and Applied Nutrition
Office of Food Safety

Overview of Oyster Irradiation

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- Goal is to kill Vv (and Vp) without changing taste or palatability.
- UF/FTSI study determined 0.82 kGy minimum dose provided required log reduction for Vv. Max. dose is <2 kGy and does not impact taste.
- Rapid process – Truckload (~37,000 pounds) of oysters can be irradiated in ~2 hours
- FTSI charges ~8 - 10 cents per pound for shell-stock oyster irradiation
- We have not yet set process parameters or established a price for shucked meats.

Keys to Oyster Irradiation

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Dose

Maintain cold chain

Approved Food-contact Packaging (not applicable to in-shell oyster irradiation)

Proper Labeling

The above must be done while maintaining an emphasis on safety and quality.

Dose

We must be able to accurately measure and document the dose range the product received. Dose expressed in kilogray (kGy)

Alanine dosimeters typical for oyster irradiation.

Alanine dosimeters are small pellets that create a "free radical" upon irradiation. The amount of free radical is measured as the dose using an instrument calibrated against standards directly traceable to NIST.

Best practice is to use dosimeters in first and last product in run and have product with dosimeters in irradiator at all times during run.

Alanine Dosimetry System

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Dose Uniformity

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Because irradiation decreases rapidly with distance, any irradiation process results in a dose range throughout the product.

This means you will have a minimum dose at some point in the product and a maximum dose at another point.

The minimum dose is set to have the desired effect (achieve required log reduction of Vv).

The maximum dose is set so that product quality is maintained. Maximum dose used may be lower than the maximum dose set by regulation.

Measure dose

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The dose range and the location of the minimum and maximum dose points are dependent on the product dimensions and density. It does not change from one pallet of the same product to another if dimensions and weight are similar.

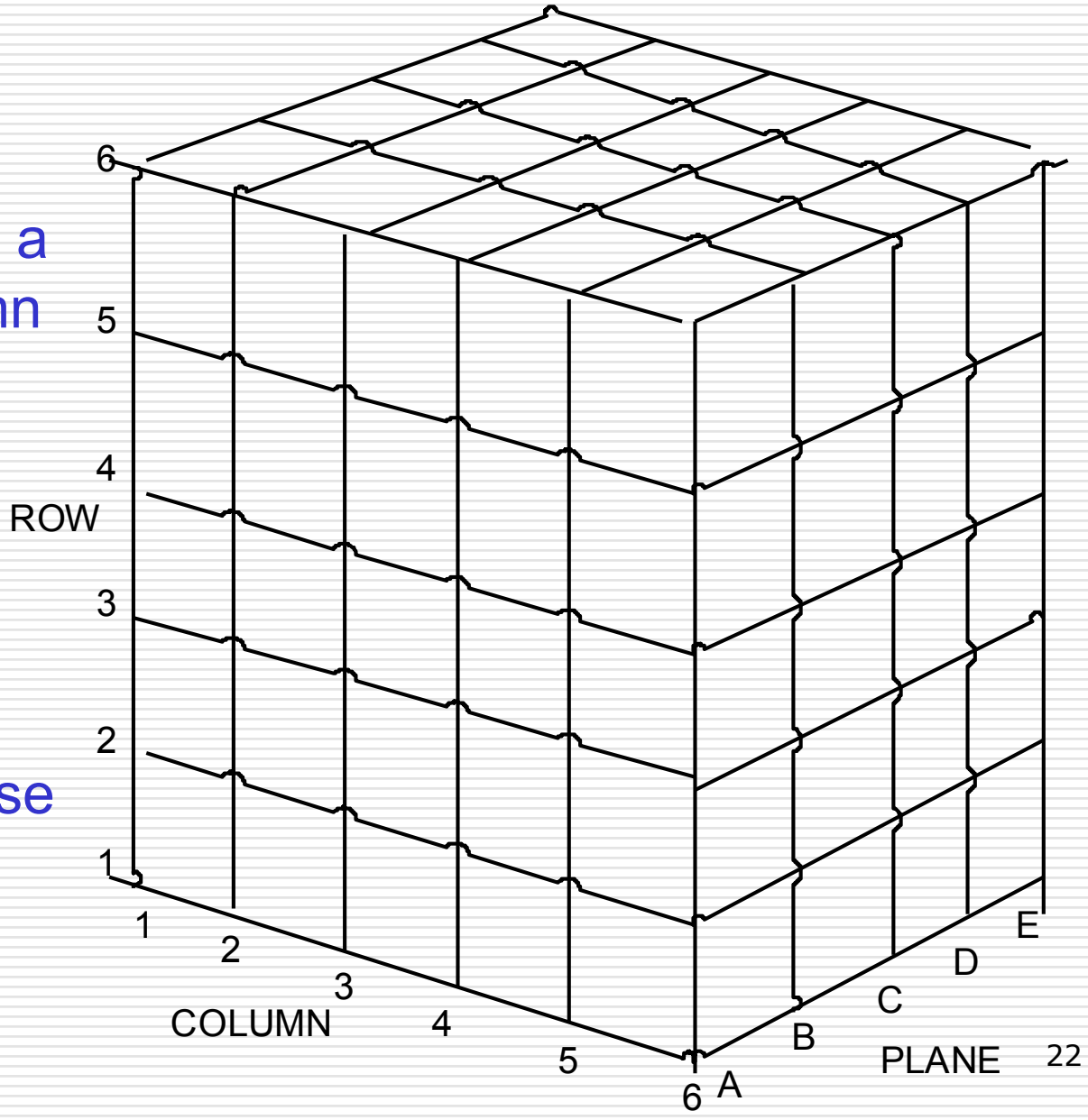
The location of the minimum and maximum doses are found by a dose map, which is placing dosimeters in a 3-dimensional pattern throughout the product.

Once those points are known, dosimeters are only used at the minimum and maximum points.

Dose Mapping

The location of each dose point is designated by a row-plane-column coordinate, e.g. 4-A-2

Dose mapping identifies the coordinate of the minimum dose point and of the maximum dose point



Dose Uniformity

For oysters, we want to keep the maximum dose as low as possible while achieving the minimum dose.

The key to this is to irradiate in half pallets to lessen the distance the radiation travels through the product. The approved validation was performed on half pallets.

Maintaining Cold Chain

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Both approved oyster irradiation facilities have cold storage.

Although the process itself does not heat the product significantly at these doses, the irradiation cell at Sterigenics - Mulberry is at ambient temperature.

This means the product will be out of refrigeration during irradiation. For oysters, this time out of refrigeration cannot exceed 2-hours.

Labeling of Irradiated Food

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- Radura and Statement required for retail sales.
  - May be on individual product box or on display label/hanger.
- Restaurant sales, etc. only require label on master container
- Modifying statements in addition to “Treated by Irradiation” such as “for Food Safety” are generally allowed.

Treated by Irradiation

Pre-labeled Product

Irradiators can apply sticker labels meeting irradiation and PHP requirements.

If producer desires to pre-label product then controls are required between point of production and irradiator. These are typically truck seals to be removed at irradiation facility.

Note – we may have to educate some State officials on how pre-label controls work. It is a very common issue and the solutions are accepted by FDA for medical devices and USDA for poultry and ground-beef.

Documentation

Sterigenics - Mullberry maintains a Quality System that meets requirements for medical devices sterilization and food irradiation. We have an approved HACCP plan for oyster irradiation and the required State permits.

Sterigenics - Mulberry produces a complete quality package for each run documenting how and when the irradiation was performed, dosimetry results, etc. that is maintained and furnished as requested.

Shelf Life

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As with most other PHPs, irradiation does accelerate the time at which oysters begin to gap.

This can be overcome with banding or by using in high-turnover outlets.

Our experience has been that the shelf-life without banding for irradiated oysters is approximately 10 days.

Taste

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Numerous taste comparisons have been made between irradiated and non-irradiated oysters over the past several years. None has found any change in taste due to irradiation.

UF used a trained panel to evaluate FTSI irradiated oysters and the panel could find no difference between irradiated and non-irradiated.

FTSI hosted a seminar for about 30 oyster producers and buyers and provided irradiated and non-irradiated oysters without telling which were irradiated. Of the 30 participants, 22 could not tell the difference, 4 correctly identified the irradiated oysters and 4 incorrectly identified the non-irradiated oysters as irradiated.

Summary

Irradiation is a highly-effective and low-cost PHP for oysters that produces an excellent product.

Two commercial irradiators in the Gulf area have experience in oyster irradiation.

Also note on 4-11-14, the FDA published a final rule notice *"…allowing ionizing radiation to control foodborne pathogens in and extend shelf life of Crustaceans (e.g., crab, shrimp, lobster, crayfish, and prawns)." "At the maximum permitted dose of 6.0 kiloGray, this will reduce, but not entirely eliminate, the number of pathogenic microorganisms in or on crustaceans."*