UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 4, 1999

MEMORANDUM TO: Frederick Sturz, Section Leader
Materials Safety and Inspection Branch, IMNS

FROM: John Jankovich
Materials Safety and Inspection Branch, IMNS

SUBJECT: MINUTES OF MEETING WITH GRAYSTAR, Inc.
MAY 11, 1999

Representatives of GrayStar, Inc., presented a briefing to the NRC staff on May 11. 1999, to describe the principles and operation of their irradiator design. The briefing was a follow-up to GrayStar's application, submitted in April 1999, for approval of the irradiator as a sealed source and device under 10 CFR 36. Mssrs. Martin Stein, President/CEO and Russell Stein. VP of GrayStar gave the presentation.

The presentation addressed the following issues:

- the need for food irradiators, bacteriological issues, consumer acceptance issues;
- reasons for selecting Cs-137 as source material;
- source construction (e.g. plugs) and testing;
- device construction, modes of operation, safety features;
- concepts and plans for source and device fabrication.

The NRC participants outlined to the GrayStar representatives that

- GrayStar must also request an application for approval as a transportation container under 10 CFR 71. NRC commenters pointed out that, for an efficient technical review, the Pt. 71 application should completed first, or conducted concurrently with a Pt. 36 evaluation, because the transportation criteria may represent the bounding conditions;
- the need for an environmental assessment will be determined later.

A set of the presentation slides is attached.

Attachment: As stated

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SSD-99-27
PDR

OFFICE	MSIB	C
NAME	JJankovichlucy	
DATE	6/ /99	

OFFICIAL RECORD COPY

GrayStar Meeting, May 11, 1999

Participants:

1. Industry

Martin H. Stein/GrayStar
Russell Stein/GrayStar
Nicolas Alfano/Ecolab Inc.
Richard Higby/Ecolab Inc.
Mark Wetterhahn/Winston & Strawn

2. Nuclear Regulatory Commission

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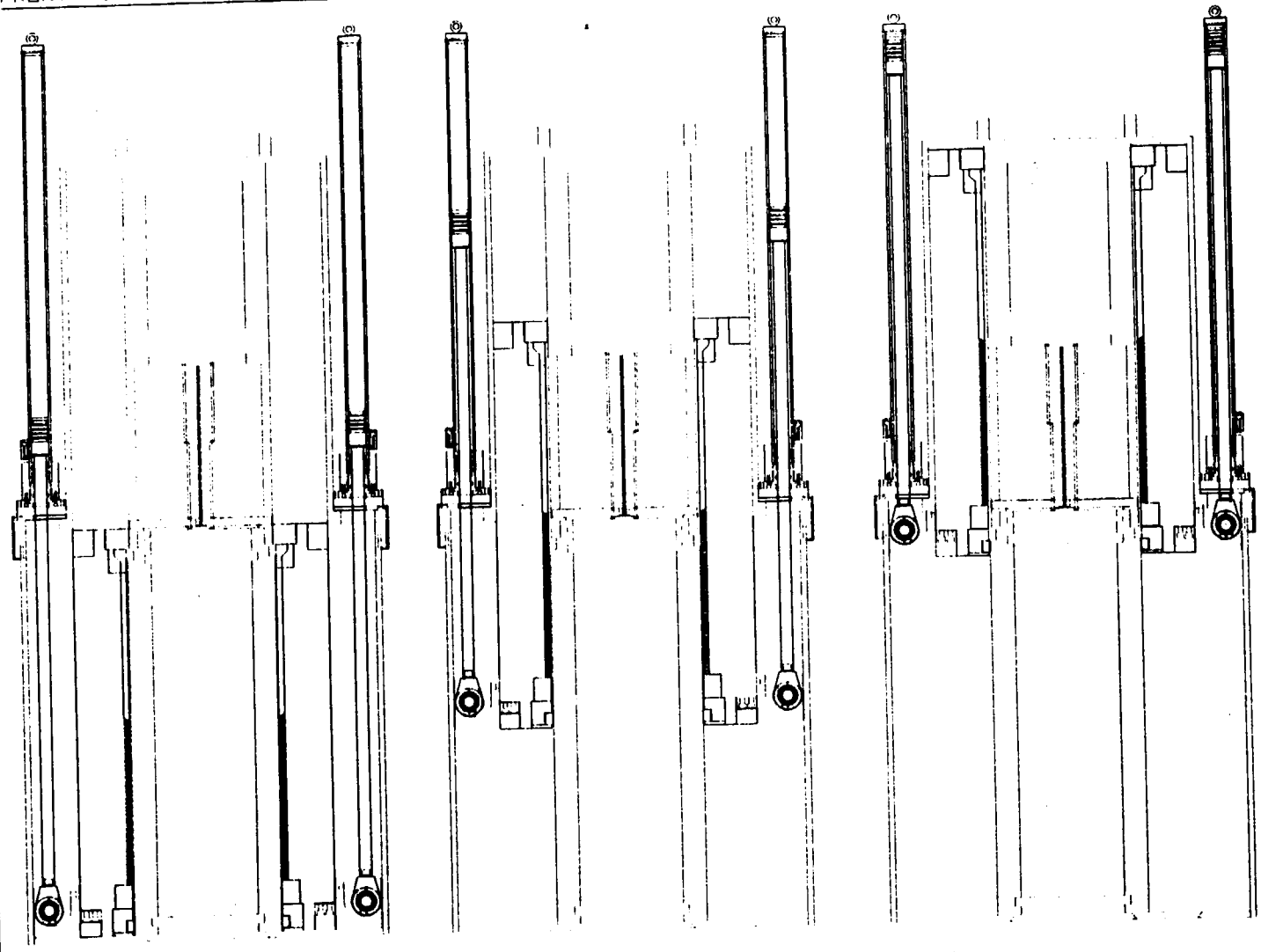
T. Kobetz/SFPO
A. Mohseni/NMSS

Attachment

FRONT VIEW CROSS SECTION



DOWN POSITION

INTERMEDIATE POSITION

UP POSITION

GRAY STAR

TITLE
ASSEMBLY DRAWING

100400

8-23-96

There are two reasons why irradiation is so effective:

1. Radiation is a volume sterilant.

   Does not rely on diffusion through materials

   "Critters" can't escape treatment

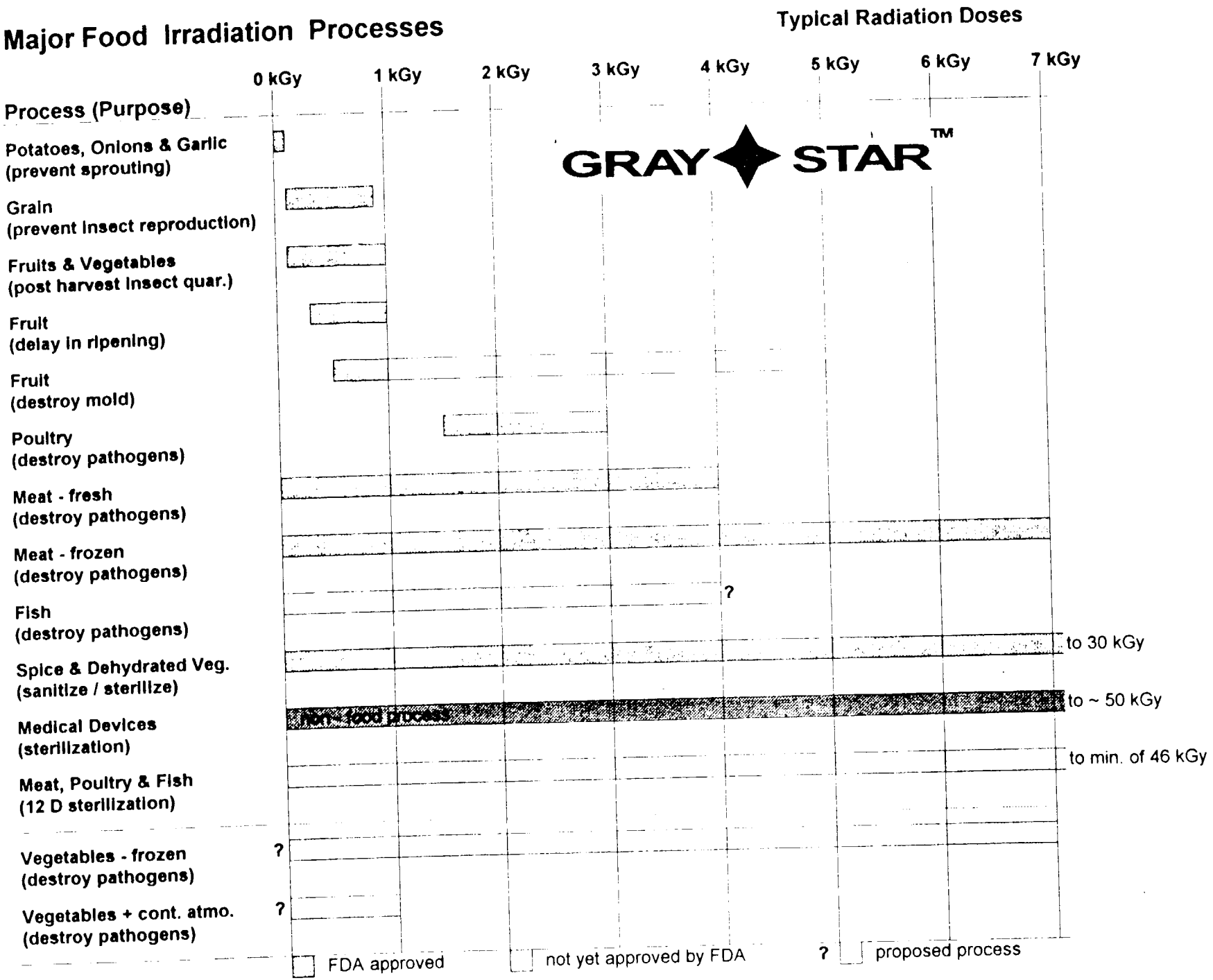
2. For most cases only one variable requires control: Total Dose

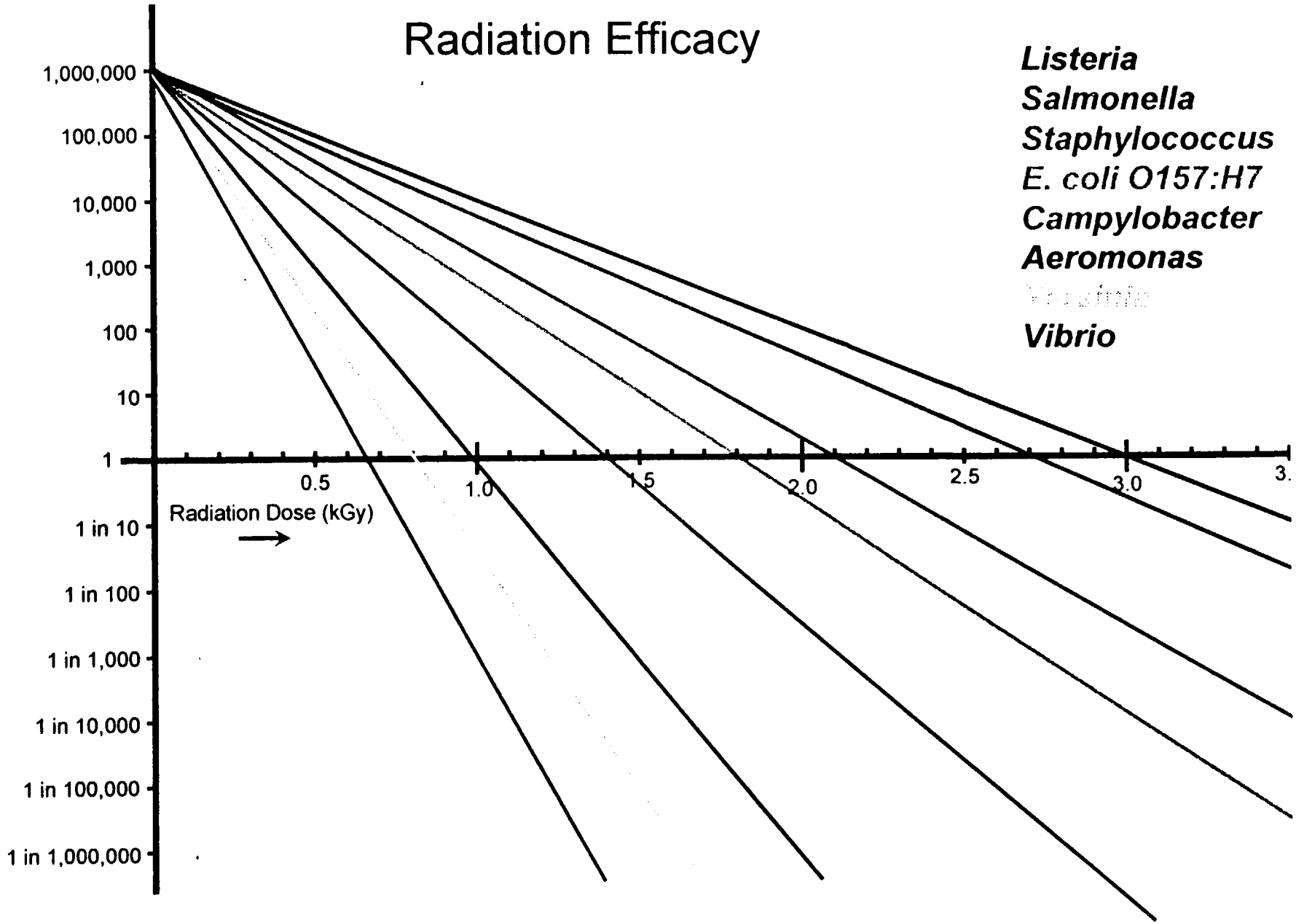
   Total absorbed dose determines effect

   Not dose rate dependent

   Validation is simple

Major Food Irradiation Processes




Radiation Efficacy
1,000,000
100,000
10,000
1,000
100
10
1
1 in 10
1 in 100
1 in 1,000
1 in 10,000
1 in 100,000
1 in 1,000,000
0.5
1.0
1.5
2.0
2.5
3.0
Radiation Dose (kGy)
Listeria
Salmonella
Staphylococcus
E. coli O157:H7
Campylobacter
Aeromonas
Vibrio

Typical Radiation Efficacy for Pathogenic Organisms

Meat, Poultry and Marine Products

Minimum radiation dose = 1.5 kGy
Average radiation dose = 2.4 kGy
Maximum radiation dose = 3.2 kGy
Typical product density = 0.43 g/cc

GRAY STAR™

Organism	Average D-Value (kGy)*	Effectiveness (log reduction) [Minimum Dose] Worst Case	[Average Dose] Typical Case (most)	[Maximum Dose] Best Case
Salmonella	0.45	3.33	5.33	7.11
Campylobacter	0.23	6.52	10.4	13.9
Listeria	0.50	3.00	4.80	6.40
Yersinia	0.13	11.5	18.5	24.6
Aeromonas	0.17	8.82	14.1	18.8
E. coli O157:H7	0.30	5.00	8.00	10.7
Vibrio	0.11	13.6	21.8	29.1
Staphylococcus	0.36**	4.17	6.67	8.89

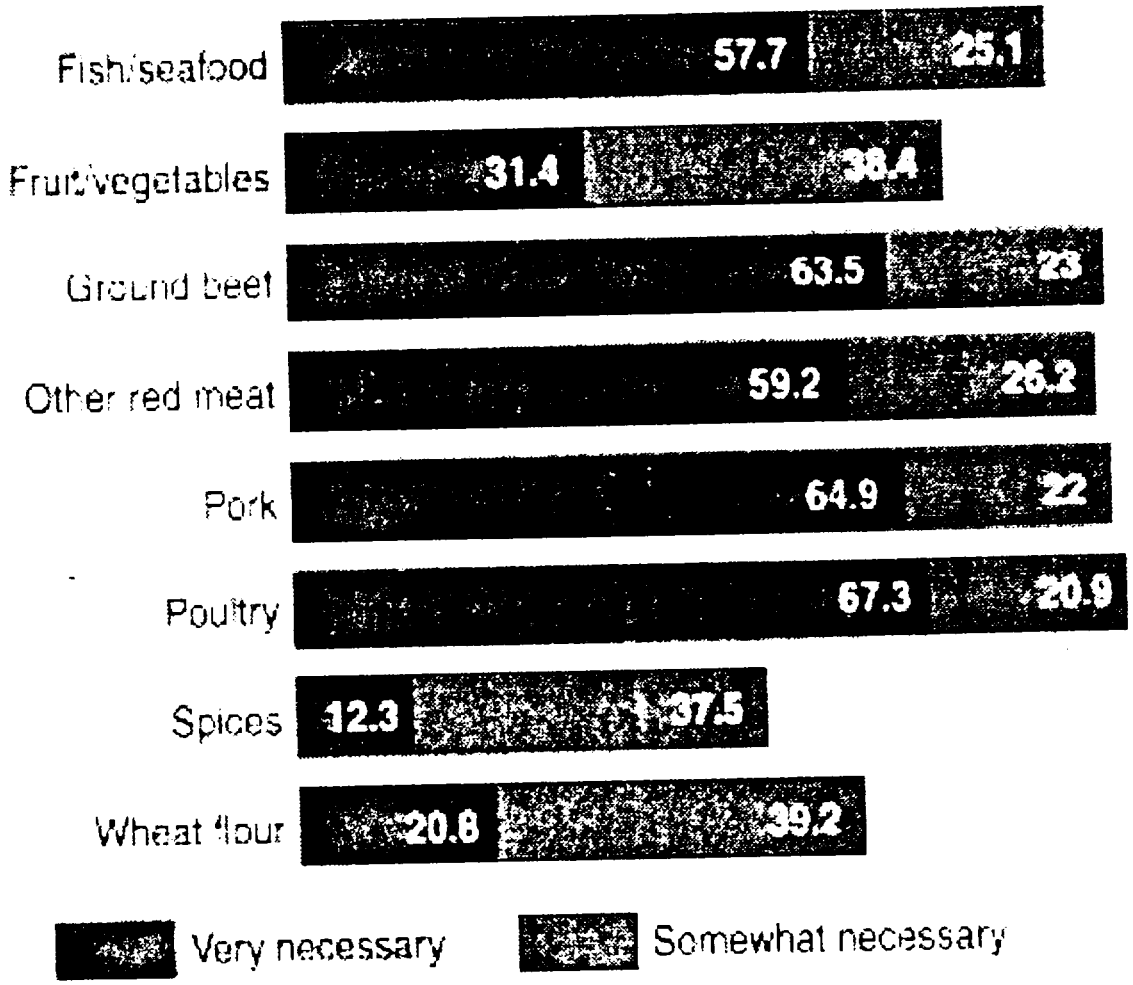
* "Food Irradiation: A Source Book", E. A. Murano, et al., Iowa State University Press, 1995

** "Gamma Ray Processing to Destroy Staphylococcus aureus in Mechanically Deboned Chicken Meat", D.W. Thayer and G. Boyd, Journal of Food Science, Volume 57, No. 4, 1992

Compiled by M. H. Stein---January 2, 1995

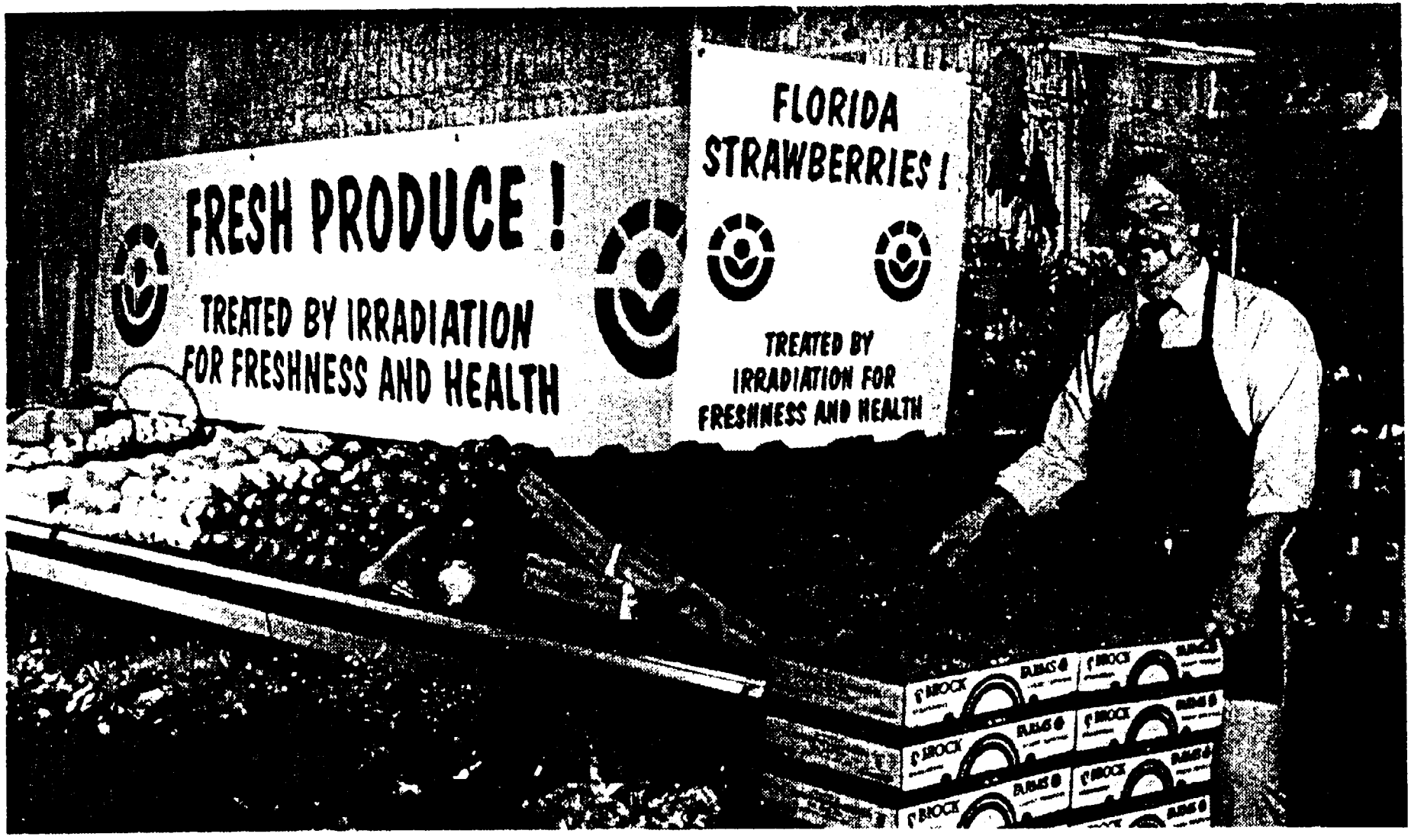
CONSUMER VIEWS

Here's a look at the percentages of consumers who view irradiation of food products as very or somewhat necessary, according to a Food Marketing Institute survey:



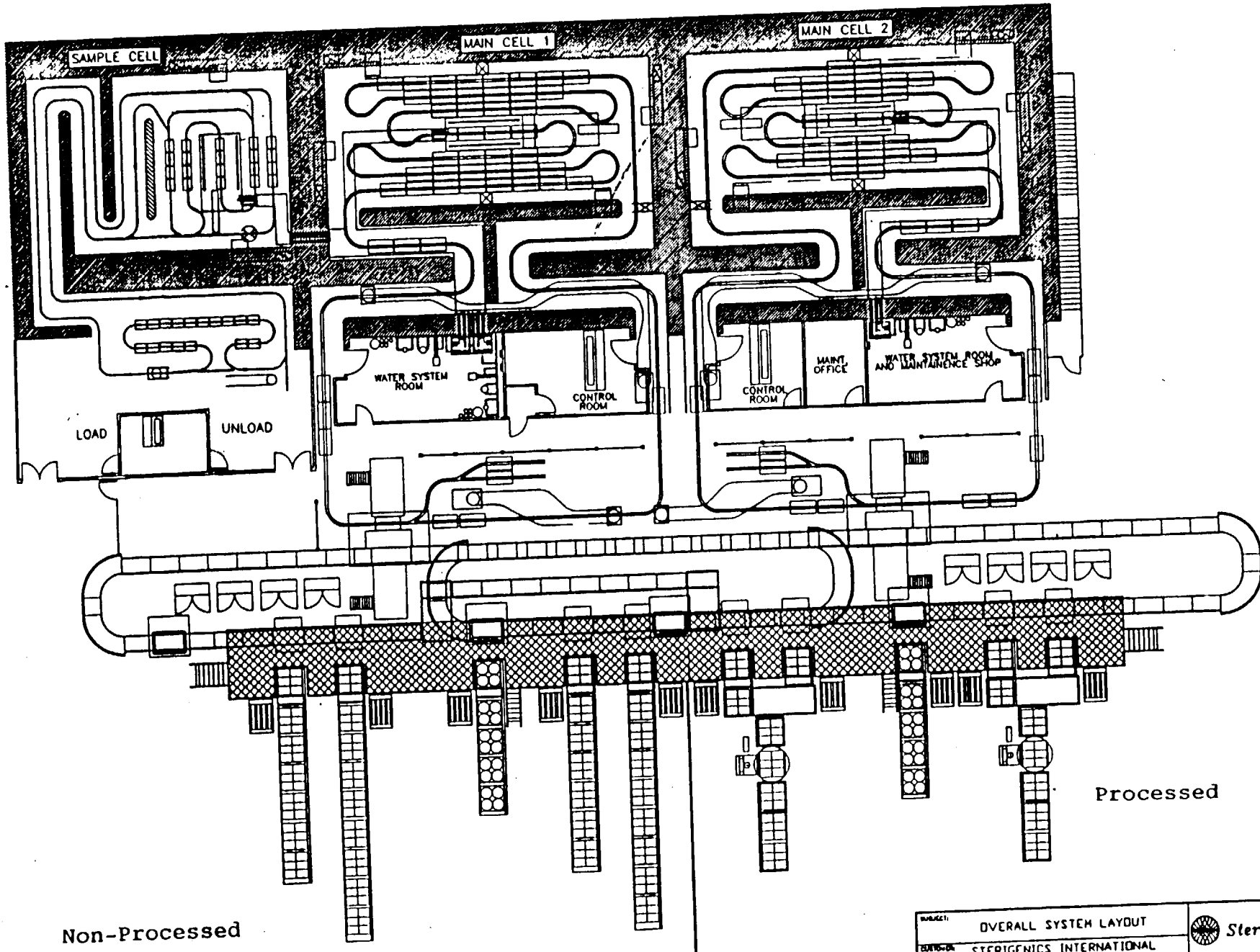
Source: Food Marketing Institute

The Packer

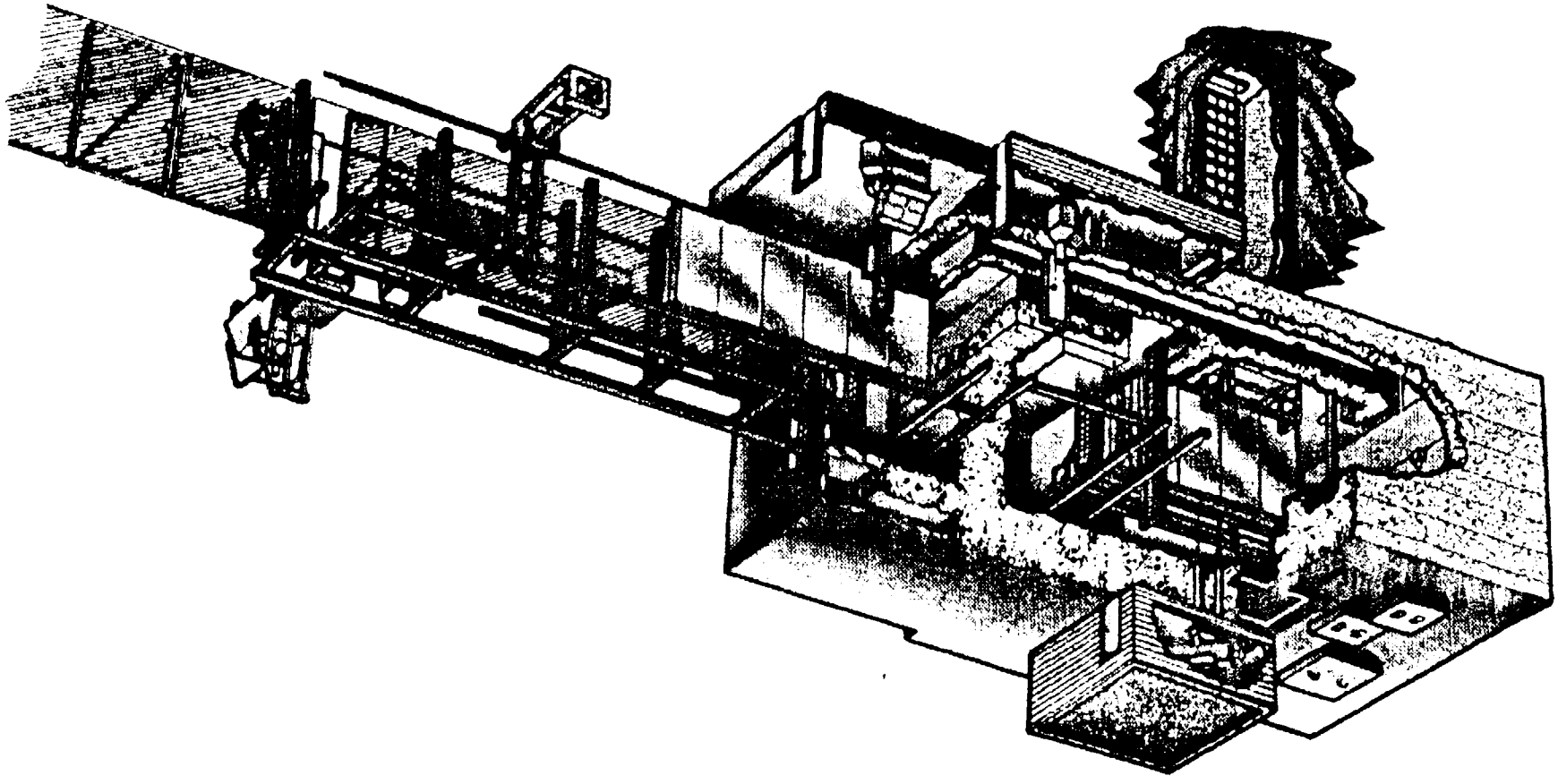

FRESH PRODUCE !
TREATED BY IRRADIATION
FOR FRESHNESS AND HEALTH
FLORIDA
STRAWBERRIES !
TREATED BY
IRRADIATION FOR
FRESHNESS AND HEALTH

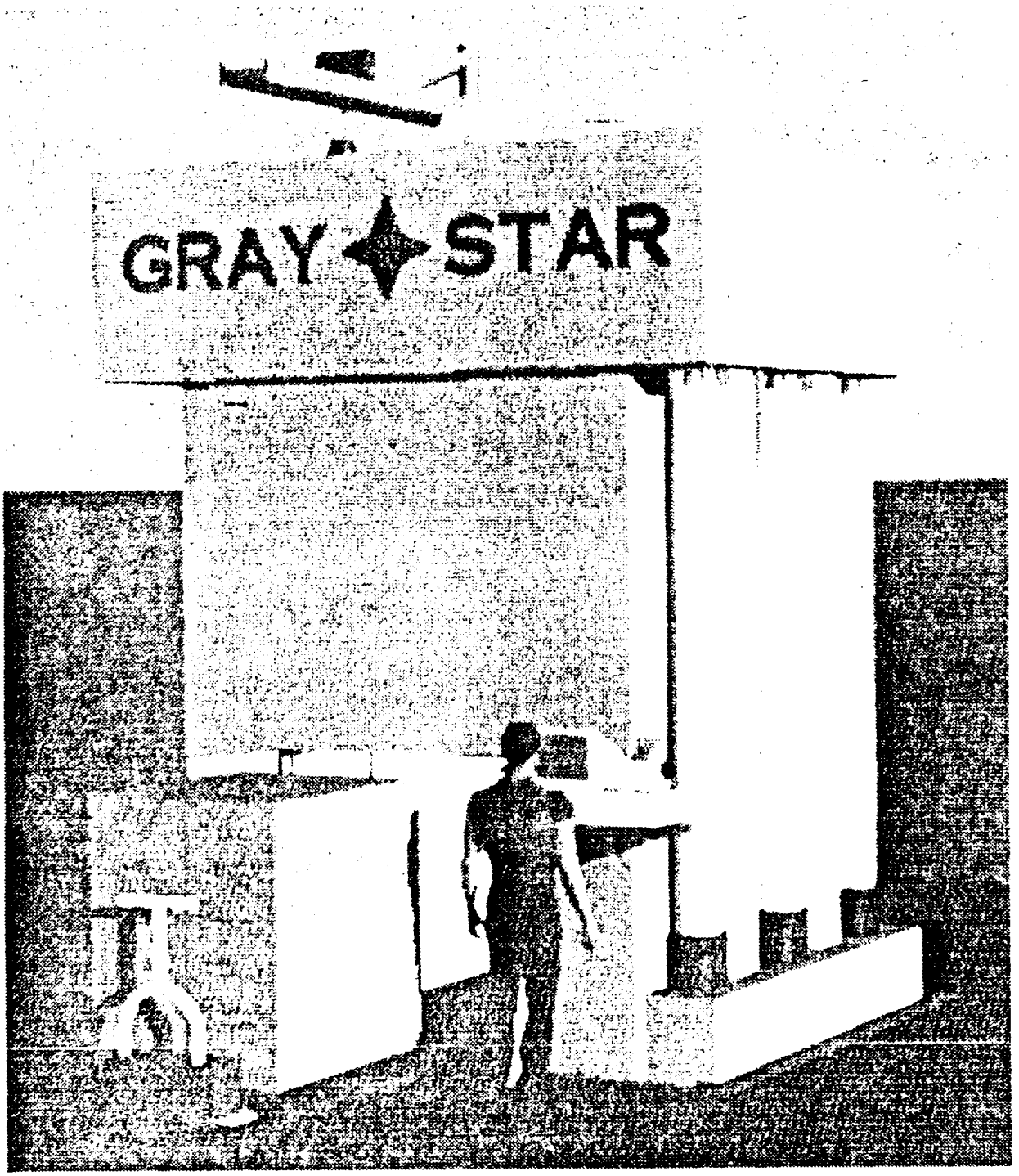
Labeling *on the packages of irradiated chicken carry the green international logo and the claim "Treated by Irradiation to control* Salmonella *and other foodborne bacteria." The product was marketed under the Nation's Pride label and distributed by the food brokerage firm, located in Plant City, Fla. (Photo courtesy of Vindicator, Inc.)*

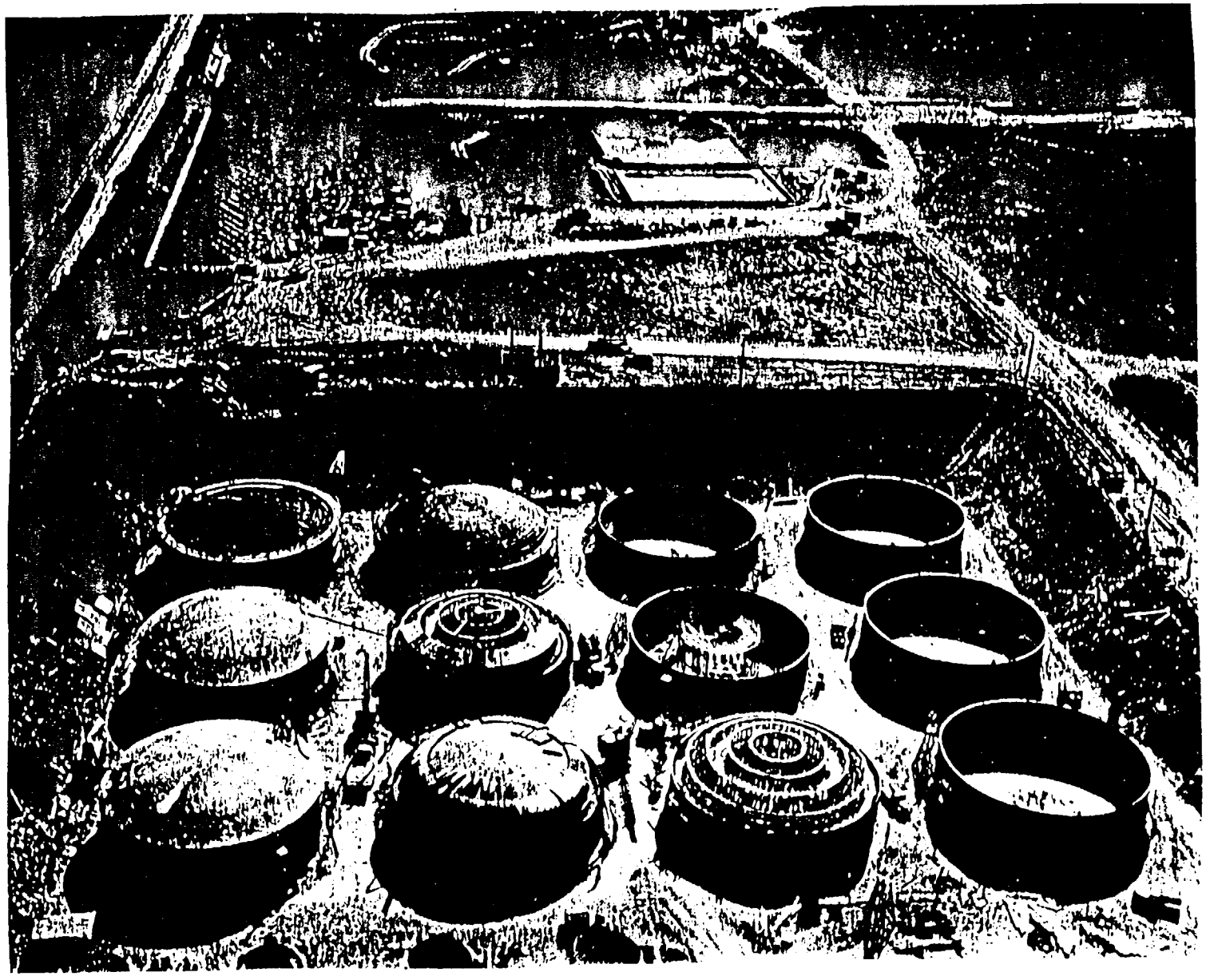
"Better than fresh, madam—everything is irradiated."



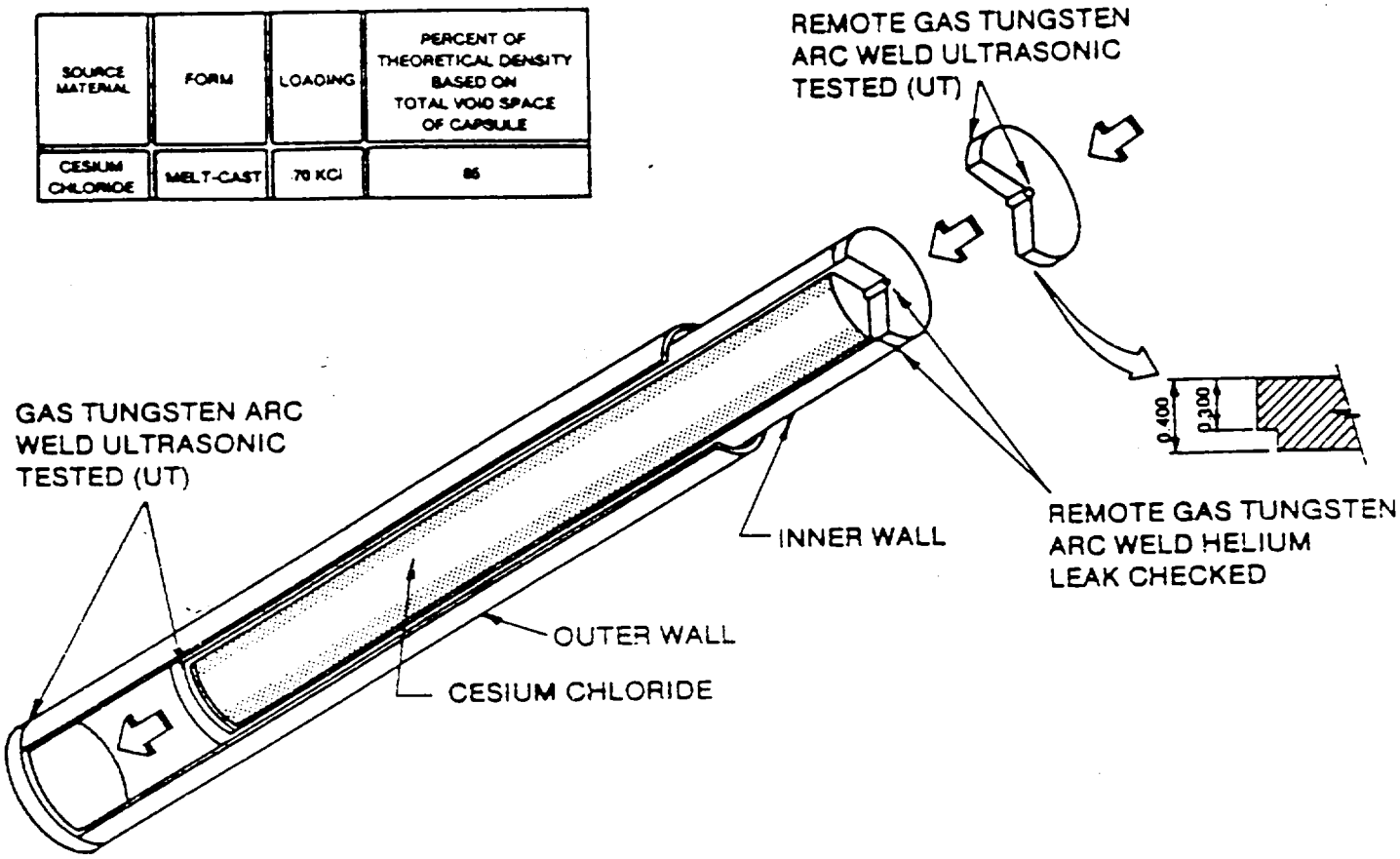
SUBJECT: OVERALL SYSTEM LAYOUT			SteriGenics
CUSTOMER: STERIGENICS INTERNATIONAL CORONA, CA			
DRAWN BY: RJD	CHECKED BY:	DATE: 10-19-94	DRAWING NO: CA-30-105 REV: 1




GRAY STAR



SOURCE MATERIAL	FORM	LOADING	PERCENT OF THEORETICAL DENSITY BASED ON TOTAL VOID SPACE OF CAPSULE
CESIUM CHLORIDE	MELT-CAST	70 KCl	85

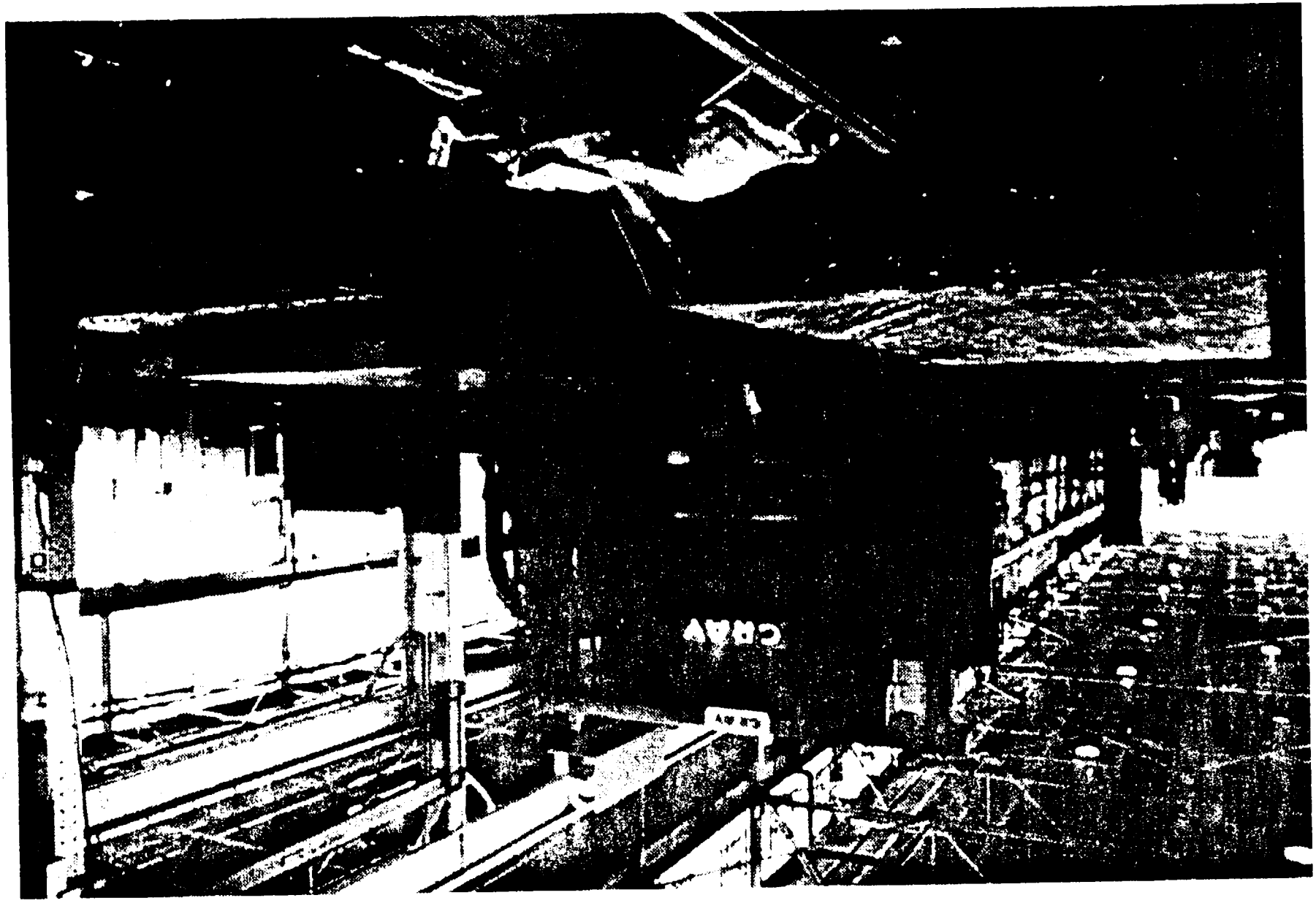


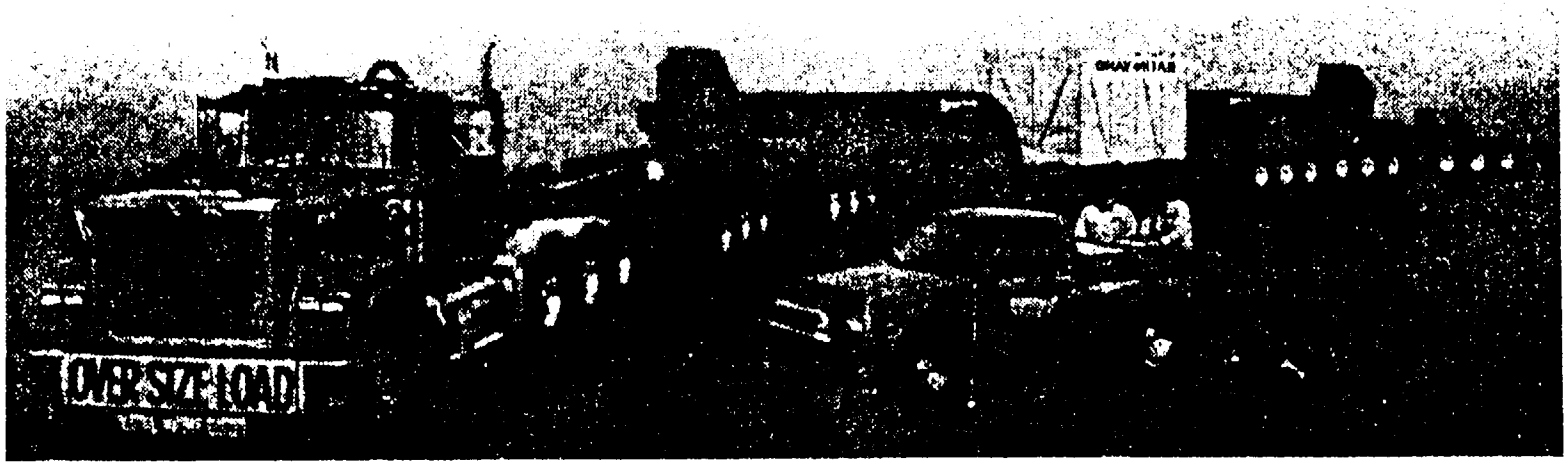
SOURCE MATERIAL	CAPSULE									
	INNER					OUTER				
	MATERIAL	WALL THICKNESS	OUTSIDE DIAMETER	TOTAL LENGTH	TOTAL CAP THICKNESS	MATERIAL	WALL THICKNESS	OUTSIDE DIAMETER	TOTAL LENGTH	TOTAL CAP THICKNESS
CESIUM CHLORIDE	316L STAINLESS STEEL (UT)	0.136 (UT)	2.250	19.725	0.400	316L STAINLESS STEEL (UT)	0.136 (UT)	2.625	20.775	0.400

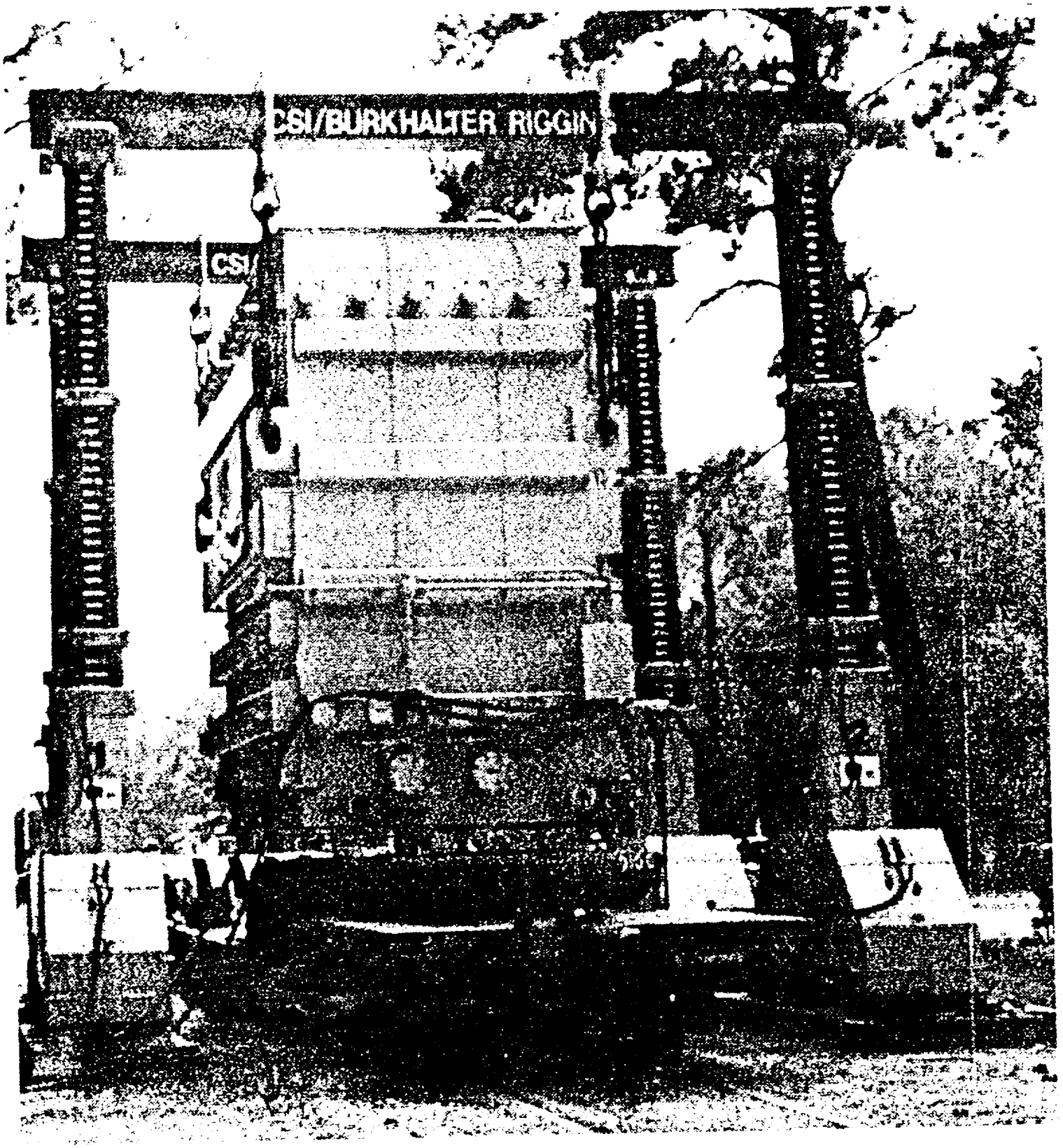
NOTE: ALL DIMENSIONS ARE IN INCHES

CESIUM-137 WESF CAPSULE

FIGURE 9


CHAV


OVERSIZE LOAD


CSI/BURKHALTER RIGGIN
CSI/