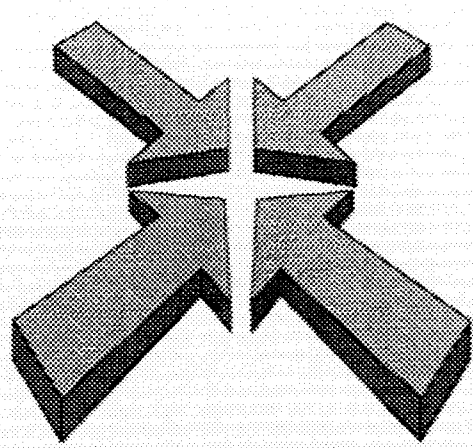
PN-ADC-835

DESCRIPTIVE FOOD ENGINEERING



DEVELOPED BY
DR. THOMAS BUTTERWORTH
AUSTIN FOODTECH

A WORKSHOP PRESENTED BY
AGRICULTURAL-LED EXPORT BUSINESSES
12 DOKKI STREET
GIZA, CAIRO
TEL 02-338-1445
FAX 02-348-0729

USAID PROJECT NO. 263-0264

Abt
Abt Associates Inc

THOMAS A. BUTTERWORTH

Austin FoodTech
114 Pearl Avenue
Newport Beach, CA 92662
TEL (714) 666-8482 FAX (714) 666-1017

EMPLOYMENT EXPERIENCE

1988-Present Managing General Partner Austin Food Tech, Inc.
-Specialists in Food Product Development

1984-1998 Instructor, "FDA Better Process Control School," Chapman University, Orange, CA

1988-1989 Lecturer, "Chemical Engineering Process Design," Department of Chemical Engineering
California State University at Long Beach

1973-1988 Associate Director, Research and Development
Beatrice/Hunt-Wesson, Inc., Fullerton, California
- Management of product/process development with staff of 24

- Project budget of $1.5 million

- Manpower assignments for product development, technical service, and non-routine regulatory interface for the following brands: Orville Redenbacher, Hunt's, Peter Pan, Fisher, J. Hungerford Smith, and Food Producers

- Experience with state-of-the-art aseptic systems, tomato products, toppings, sauces, dry mixes, drink bases, low-acid canned foods and fruits for both food service and retail product lines

- Staff commercialized 32 new products and line extensions and 30 product improvements in a five year period

1982 Instructor, "Food Engineering"
Dept. of Food Science and Technology
Chapman University, Orange, California

1980 -1981 Lecturer, "Chemical Engineering Process Design"
Dept. of Chemical, Nuclear and Thermal Engineering
University of California at Los Angeles

1968 -1973 Teaching and Research Assistantship
Dept. of Nutrition and Food Science
MIT, Cambridge, Massachusetts

1968 Chemical Engineer
Western Regional Research Laboratory, Albany, CA
- Work resulted in three publications

1964 - 1967 Chemical Engineer
B.F. Goodrich Chemical Company, Long Beach, CA

EDUCATION

Ph.D., Biochemical Engineering, 1973
Massachusetts Institute of Technology
- Chemical Engineering and Biology minors
- Thesis project concerned separation of protein solutions by ultrafiltration covered in two publications.
- Recipient of Nestle-IFT Fellowship

B.S., Chemical Engineering, 1967
University of California at Berkeley

PROFESSIONAL AFFILIATIONS

Institute of Food Technologists:
-Former Chairman, Food Engineering Division and
Former Member, Annual Program Committee
Institute for Thermal Processing Specialists
American Assoc. for the Advancement of Science
Industry Advisory Council, Food Science and
Technology Department, Univ. Calif. Davis
Food Engineering Advisory Council, Univ. Calif. Davis

REGISTRATION INFORMATION

FOOD ENGINEERING

Name _____

Title _____

Company _____

Address _____

_____

TEL _____

FAX _____

Email _____

I will attend the program in

CAIRO ☐ ALEXANDRIA ☐

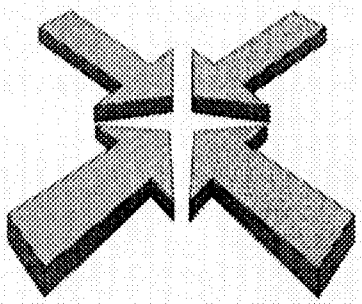
Attendess may register by calling in or faxing this registration to ALEB. They may also register on-site. Please let us know if you plan to attend so that we can plan appropriatley.

There will be a 100LE registration for this program. Registrants will receive a course notebook, lunches and coffee breaks morning and afternoon on each day and a certificate of participation.

For further details, contact:

Agriculture Led Export Businesses (ALEB)
12 Dokki Street
Dokki, Cairo, EGYPT
TEL 202-338-1445 (6 Lines)
FAX 202-348-0729

DESCRIPTIVE FOOD ENGINEERING



A SHORT COURSE IN A SERIES SPONSORED BY THE AGRICULTURE LED EXPORT BUSINESSES PROJECT (ALEB) CAIRO, EGYPT & THE CENTER FOR ADVANCED FOOD TECHNOLOGY PISCATAWAY, NJ, USA

USAID Contract No. 263-0264

October 16, 2000 at 9:30 at the Hotel Mercure, Alexandria
October 17, 2000 at 9:00 at the ALEB Training Center
12 Dokki Street, 5th Floor

DESCRIPTIVE FOOD ENGINEERING

Dr. Thomas A. Butterworth, Consultant to ALEB, has been in Egypt for six weeks, both in winter and spring. During this time he visited 18 food processors throughout the country. During these visits he noticed that some of the people were asking about many of the same things and many of the facilities were trying to solve similar operational concerns.

This course is intended to emphasize these common threads that are both engineering-oriented and subject to improvement. The specific subjects to be covered are as follows:

How to Control Headspace

Definitions, importance of headspace; factors that control headspace and common methods to control these factors

How to Control Vacuum

Definitions, importance and normal ranges of vacuum; factors that control vacuum and common methods to achieve and control these factors

How to Bring Horizontal Still Retorts into Compliance with U.S. Regulations

A review of the applicable regulation including specific design criteria and equipment specifications

Some Common Sanitation Problems and How to Avoid Them

A retrospective of some of on GMP's and sanitary practices & Dr. Butterworth's observations while in Egypt

Design of Batch Processes

A summary of how to design batch processes in terms of how to specify the number of batch operations and ingredient flow rates required for the specified line speed.

How to Calculate Heating Time in a Kettle

A review of elementary heat transfer as it applies to heating liquid in a jacketed kettle. Handout and explanation of a floppy disk which will enable the attendee to make his own calculations, customized for any facility.

How to Make a Preliminary Estimate of Capital Costs

A method of estimating preliminary capital costs of either new installations or expansions of existing facilities. Such an estimate can be made with knowledge only of the uninstalled cost of the major equipment.

INSTRUCTOR

Dr. Thomas Butterworth
Managing General Partner
Austin FoodTech
114 Pearl Street
Newport Beach, CA 92662
TEL (714) 666-8482
FAX (714) 666-1017

Dr. Butterworth has been actively involved in the food industry for over 25 years. He managed the process/product development group at Hunt Wesson Foods. The group commercialized 32 new products & line extensions, plus made numerous product improvements. He founded Austin FoodTech in 1988.

FOR MORE INFORMATION

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Mr. Morad S. Ahmed
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Monhandseen, Cairo
TEL 338-1445
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EMAIL rfstier4@egyptonline.com
morad@egyptonline.com

October 16, 2000
9:30 – 17:00
Mercure Hotel
ALEXANDRIA

October 17, 2000
9:30 – 17:00
ALEB Training Room
ALEB Offices

The course in intended to be descriptive and applied in nature with minimal emphasis on theory or mathematics.

Descriptive Food Engineering

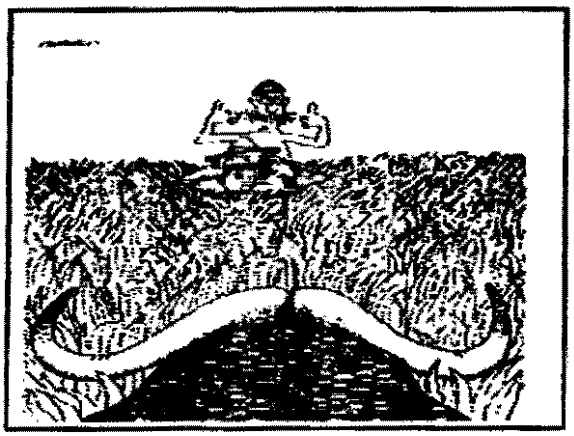
- Thomas A. Butterworth, Ph.D.
- Austin Food Tech, Inc.
- Consultant for ALEB

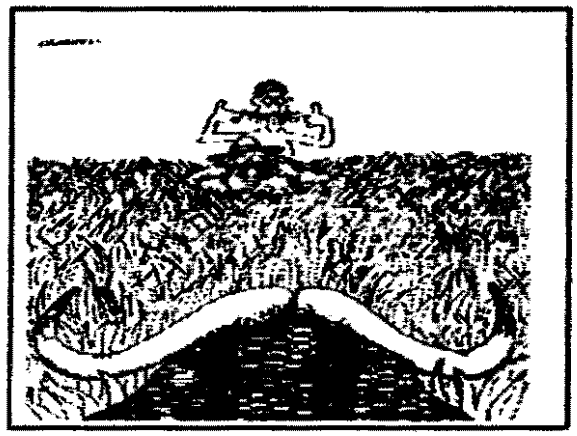
- E-mail: foodtech@compuserve.com
- www.austinfoodtech.com

الهندسة الوصفية للأغذية

- د. توماس أ. باتروورث
- أوستن فود تك، إنك.
- خبير استشاري لمشروع ALEB

- البريد الإلكتروني: foodtech@compuserve.com
- www.austinfoodtech.com





How to Control Headspace in a Canned Product

كيفية التحكم في الحيز الطوي الموجود في المنتج المطب

§113.3 Definitions.

(h) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

§ ١١٣,٣ تعريفات

(ح) "إجمالي الحيز العلوي" هو المسافة الرأسية بين مستوى المنتج (عادة ما يكون السطح السائل) في حاوية صلبة مستقيمة بشكل عمودي والحافة العلوية من الحاوية (عند حافة اللحام المزدوج للعلبة أو الحافة العلوية من البرطمان الزجاجي).

§113.3 Definitions.

(i) "Headspace, net" of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

§ ١١٣,٣ تعريفات

(ط) "صافي الحيز العلوي" هو المسافة الرأسية بين مستوى المنتج (عادة ما يكون السطح السائل) في حاوية صلبة مستقيمة بشكل عمودي والسطح الداخلي من الغطاء.

How to Control Headspace In a Canned Product

- Control variations in:
  - Net weight
  - Air content
  - Fill height
  - Container size
  - Fill temperature
  - Amount of primary fill (eg. Beans)

كيفية التحكم في الحيز العلوي الموجود في المنتج المعلب

- اختلافات التحكم في:
  - صافي الوزن
  - محتوى الهواء
  - ارتفاع الملء
  - حجم الحاوية
  - درجة حرارة الملء
  - كمية الملء المبدئي (مثلاً الفول)

Why is Headspace Important?

- Affects vacuum
- Affects net weight and therefore cost

لماذا يكون الحيز العلوي هاماً؟

- لأنه يؤثر في الفراغ
- لأنه يؤثر في صافي الوزن وبالتالي التكلفة

Why is Headspace Important?

- At times a critical factor in thermal processing
- Excessive headspace could:
  - Lose customers
  - Be in violation of regulations

لماذا يكون الحيز العلوي هاماً؟

- لأنه يكون في بعض الاحيان عاملاً حرجاً في المعالجة الحرارية
- يمكن الحيز العلوي الزائد أن يتسبب في:
  - فقد العملاء
  - انتهاك القوانين

How to Control Headspace In a Canned Product

- Control variations in:
  - Net weight
  - Air content
  - Fill height
  - Container size
  - Fill temperature
  - Amount of primary fill (eg. Beans)

كيفية التحكم في الحيز العلوي الموجود في المنتج المعلب

- لمتغيرات التحكم في:
  - صافي الوزن
  - محتوى الهواء
  - ارتفاع الملء
  - حجم العلبة
  - درجة حرارة الملء
  - كمية الملء الاولى (مثلاً الفول)

Controlling Net Weight

- Weight control program as part of Quality Control:
  - –Communication between Q.C. lab and filler operator
- Accurate filling operation(s)
- On-line check-weighers

التحكم في صافي الوزن ومراقبته

- برنامج التحكم في الوزن كجزء من عملية مراقبة الجودة
- – الاتصال بين معمل مراقبة الجودة ومن يقوم بتشغيل المالئ
- عملية (عمليات) الملء الدقيقة
- أجهزة قياس الوزن المُراقبة اللحظية

Controlling Air Content

- Filling without introducing air
- Deaeration prior to filling
- Filling with a vacuum assist

التحكم في محتوى الهواء ومراقبته

- القيام بالملء دون إدخال الهواء
- نزع الهواء قبل الملء
- الملء عن طريق التفريغ الهوائي

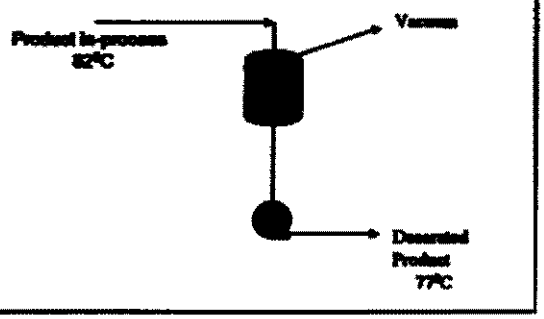
Filling Without Adding Air

- Air may be introduced through filler seals or by splashing
- May require slowing line speed

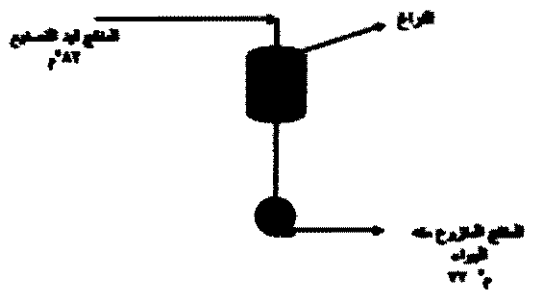
الملء دون إضافة الهواء

- يمكن إدخال الهواء من خلال سدادات المالئ أو عن طريق الرش
- قد يتطلب الأمر إبطاء سرعة خط الانتاج

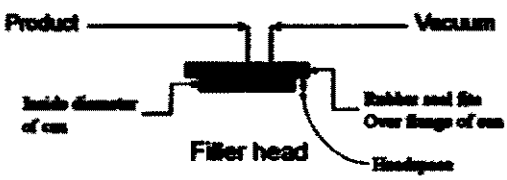
De-aeration



نزع الهواء

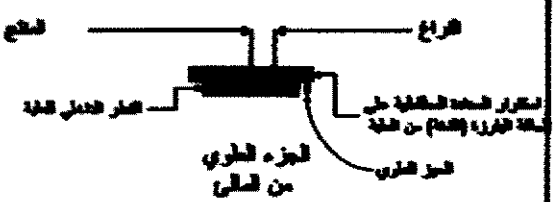


Filling with Vacuum Assist



First vacuum is pulled on can and
then is released by filling with product

الملء عن طريق التفريغ الهوائي



If All Else Fails

Try a "tilt rail" for automatic
headspace control

إذا أخفقت كافة العمليات الأخرى

Tilt Rail

A "tilt rail" is a strip of stainless steel over which the cans pass just before seaming.This "rail" lifts one side of each can a prescribed amount and spills excess product to the floor.

القضيب المائل

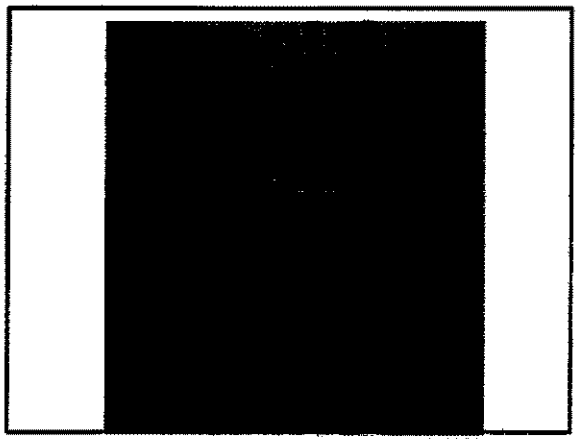
- "القضيب المائل" يكون عبارة عن شريحة من فولاذ لا يصدأ تمر عليه العلب المعدنية مباشرة قبل عملية اللحام الدرزي. يقوم هذا "القضيب" برفع جانب واحد من كل علبة بالقدر المحدد مسبقاً ثم يقوم بسكب ما يزيد من المنتج على الارض.

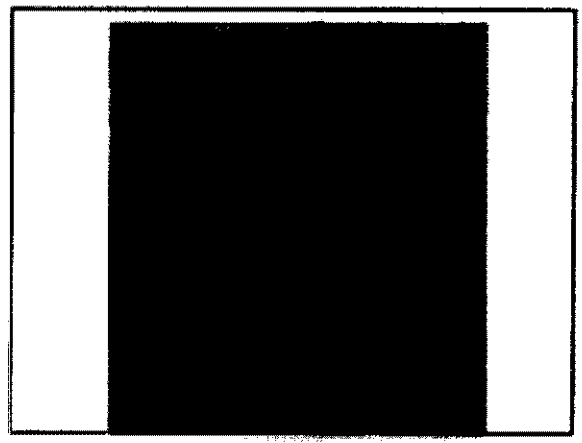
Disadvantages of a Tilt Rail

- Wastes product
- May create sanitation problems

مساوئ القضيب المائل

- يهدر المنتج
- قد يسبب بعض المشكلات المتعلقة بالنظافة





How to Create and Control Vacuum in a Canned Product

كيفية تكوين فراغ والتحكم فيه داخل منتج معلب

How to Create Vacuum in a Canned Product

- What is vacuum?
- How is vacuum measured?
- Why is vacuum important?
- How much vacuum is needed?
- How to achieve it...

كيفية تكوين فراغ داخل منتج معلب

- ما هو الفراغ؟
- كيف يتم قياس الفراغ؟
- لماذا يكون الفراغ هاماً؟
- ما هو حجم الفراغ المطلوب؟
- كيف يمكن تحقيقه...

What is Vacuum?

"A degree of rarefaction well below atmospheric pressure..."

Webster's Dictionary

ما هو الفراغ؟

"هو درجة من التخلخل

أي انخفاض الضغط بشكل

كبير عن الضغط الجوي..."

قاموس ويبستر

What is Vacuum?

A measure of the extent to which air has been removed from a hermetically sealed container

ما هو الفراغ؟

هو قياس مقدار

نزع الهواء من الوعاء المغلق

بشكل محكم ومانع للتسرب

Zero Vacuum

...the pressure in the headspace is equal to atmospheric pressure.

الفراغ صفر

...يكون الضغط داخل الحيز

العلوي مساوياً للضغط الجوي

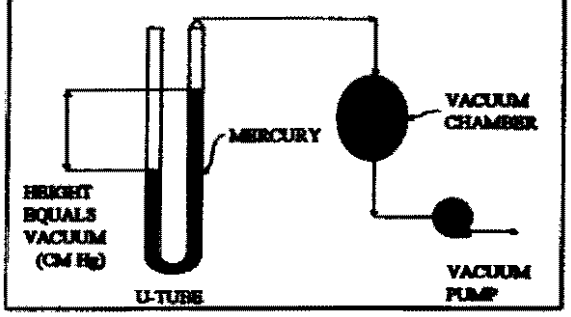
Full Vacuum

...all gas has been removed from the container (76 cm Hg)

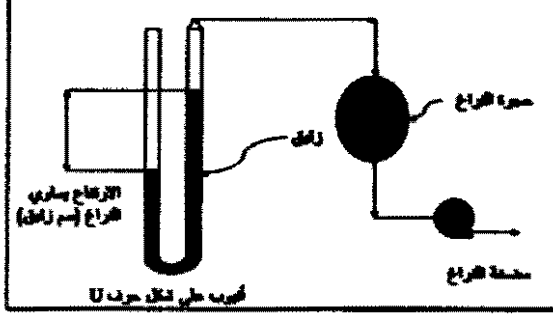
الفراغ الكامل

..تمت إزالة الغاز كلية من
الحاوية (٧٦سم زئبق)

How is Vacuum Measured?



كيف يتم قياس الفراغ؟



Why is Vacuum Important?

- Vacuum maintains the can ends or jar closures in a concave position, giving a visual index to the condition of the contents

لماذا يكون الفراغ هاماً؟

- يكون الفراغ هاماً لأنه يحتفظ بأطراف العلب أو الأغطية المحكمة البرطمانات في وضع مقعر، مما يعطي دليلاً مرئياً عن حالة المحتويات بالداخل

Why is Vacuum Important?

- Vacuum reduces the quantity of oxygen in the container, delaying oxidative reactions such as darkening, lipid oxidation and can corrosion

لماذا يكون الفراغ هاماً؟

- يقلل الفراغ من كمية الأكسجين داخل الحاوية، الأمر الذي يؤخر من حدوث التفاعلات المؤكسدة مثل الاعتام وتأكسد الدهون وتآكل العلبة المعدنية

Why Is Vacuum Important?

- Vacuum prevents permanent distortion of can ends and helps hold the closure on glass-packed products during thermal processing.

لماذا يكون الفراغ هاماً؟

• يمنع الفراغ تشوه أطراف العلب المعدنية ويعمل على ابقاء غطاء الغلق في مكانه باحكام على المنتجات المعبأة في حاويات زجاجية أثناء المعالجة الحرارية

How Much Vacuum Is Needed?

- Varies with salt content, pH of the product and type of container

ما هو حجم الفراغ المطلوب؟

• يختلف هذا الامر حسب محتوى الملح ودرجة الحموضة ونوع الحاوية.

How Much Vacuum Is Needed?

- Minimum: 13 cm Hg
- Ideal range: 24 to 38 cm Hg

  Any vacuum over about 45 cm Hg could cause paneling, high removal torque or inability to use lighter cans

ما هو حجم الفراغ المطلوب؟

• الحد الادنى هو: ١٣ سم زئبق
• الحد المثالي: يتراوح ما بين ٢٤ إلى ٣٨ سم زئبق

أي فراغ يزيد عن ٤٥ سم زئبق يتسبب في تحطم جوانب العلبة ويزيد من قوة الضغط عليها أو يسبب عدم القدرة على استخدام العلب الخفيفة.

Methods of Achieving Vacuum

- Hot filling
- Mechanical application of vacuum
- Steam displacement of headspace air

طرق إحداث الفراغ

- الملء الساخن
- الاستخدام الميكانيكي للفراغ
- إزاحة البخار للهواء الموجود بالحيز العلوي

Hot Filling

- The product is heated to 75 to 90°C prior to closing.

  Note: For this discussion a thermal exhaust system will create vacuum in the same way as hot filling.

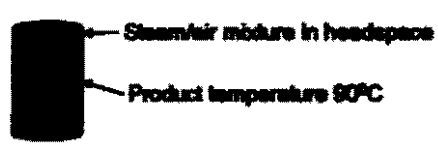
الملء الساخن

- يتم تسخين المنتج حتى ٧٥ – ٩٠°م قبل الغلق.

ملحوظة: يجدر الاشارة الى ان نظام التفريغ الحراري سوف يكون الفراغ بنفس طريقة الملء الساخن.

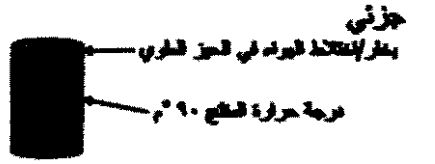
Hot Filling (Cont)

- This temperature creates an atmosphere in the headspace which contains partly steam.



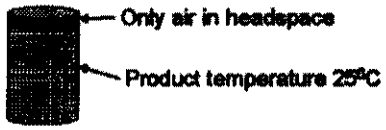
الملء الساخن (تابع)

- تشكل درجة الحرارة المذكورة هواء في الحيز العلوي الذي يحتوي على بخار بشكل جزئي



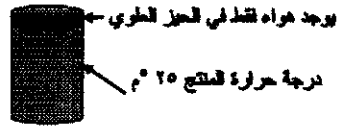
Hot Filling (Cont)

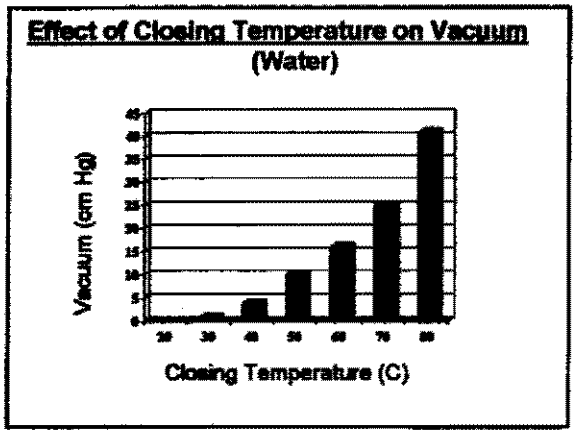
- The steam condenses and contracts when cooled, thereby forming a partial vacuum.

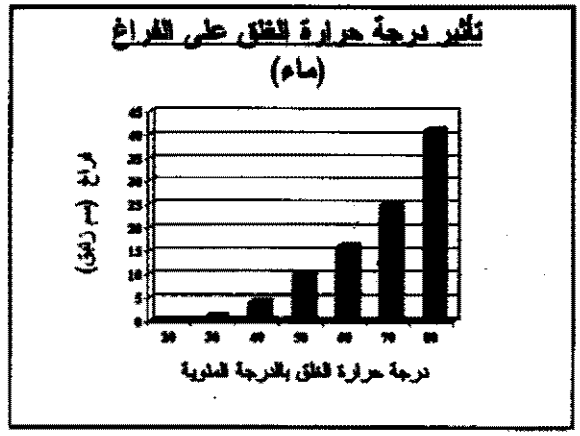


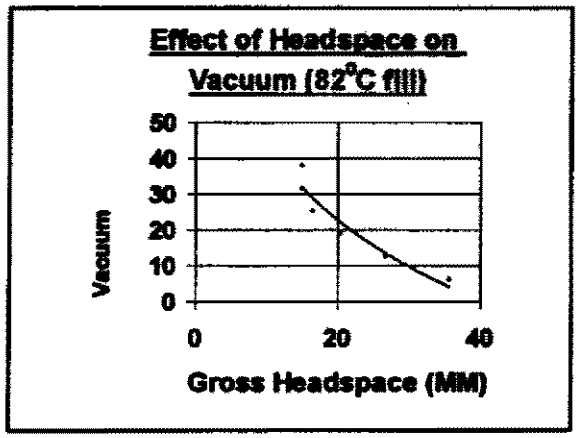
الملء الساخن (تابع)

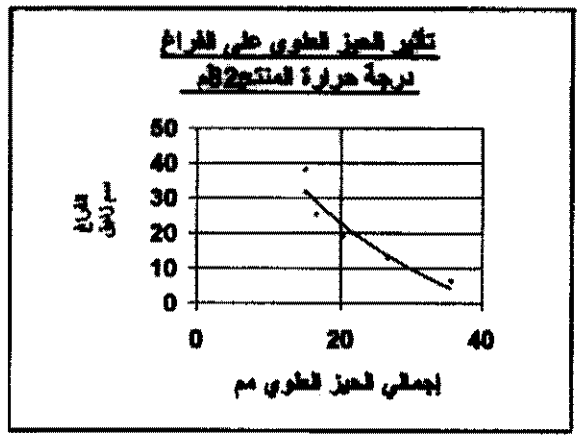
- يتكثف البخار وينقلص عندما يبرد حيث يتكون بمقتضاه فراغاً جزئياً.











Mechanical Application of Vacuum

A portion of the container headspace gas is pumped out by a vacuum pump:

Very slow

Sometimes used for pouches

الاستخدام الميكانيكي للفراغ

يتم تفريغ جزء من الغاز الموجود في الحيز العلوي بواسطة مضخة تعمل بالتفريغ الهوائي:

هذه العملية تكون شديدة البطء

تستخدم في بعض الاحيان في الاكياس

Steam Displacement of Headspace Gas

- Steam is injected into the headspace
- The steam replaces some of the air

إزاحة البخار للغاز الموجود في الحيز العلوي

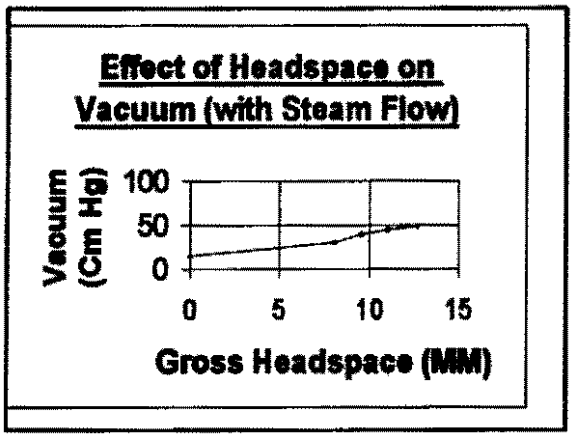
- يتم حقن البخار داخل الحيز العلوي
- يحل البخار محل بعض الهواء الموجود

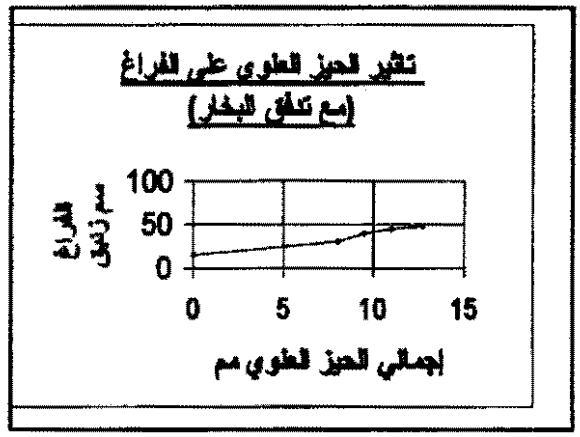
Steam Displacement of Headspace Gas (Cont)

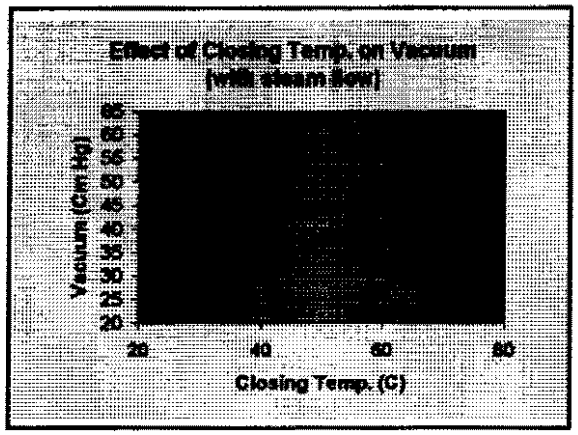
- The container is sealed immediately
- Vacuum is produced when the steam condenses

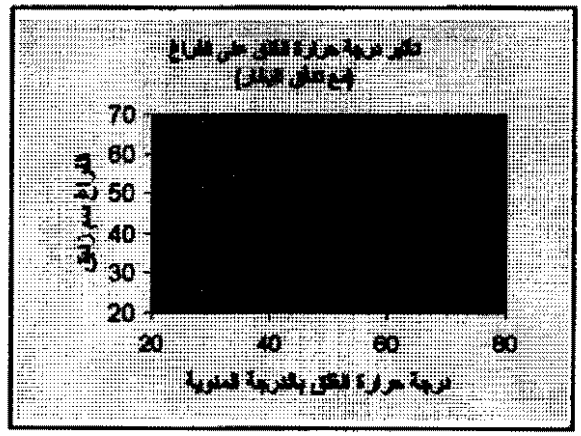
إزاحة البخار للغاز الموجود في الحيز العلوي (تابع)

- يتم إقفال الحاوية مباشرة بإحكام
- ينتج الفراغ عندما يتكثف البخار









Vacuum is Affected by:

- Fill temperature
- Headspace
- Exhaust box
- Steam flow
- Mechanical application

يتأثر الفراغ بما يلي:

- درجة حرارة الملء
- الحيز العلوي
- صندوق التفريغ
- تدفق البخار
- التطبيق الميكانيكي

How to Bring a Horizontal Still Retort into Compliance with U.S. Regulations

كيفية جعل جهاز تعقيم ثابت أفقي مطابقاً للوائح الأمريكية

21 CFR Part 113
Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

http://www.access.gpo.gov/nara/cfr

القانون الامريكي للوائح الفيدرالية ٢١
الجزء ١١٣
الاغذية المصنعة حرارياً المحتوية على نسبة منخفضة من الحامض والمعبأة داخل حاويات محكمة الاغلاق

http://www.access.gpo.gov/nara/cfr

Horizontal Still Retorts

Design Criteria:

- Mercury-in-glass thermometer (MIG)
- Temperature recorder
- Steam spreader
- Automatic steam controller
- Bleeders
- Vents
- All valves
- Stacking equipment

أجهزة التعقيم الأفقية الثابتة

• معايير التصميم:

- ترمومتر زجاجي زئبقي (MIG)
- جهاز تسجيل درجة الحرارة
- جهاز نشر البخار
- جهاز التحكم الاوتوماتيكي في البخار
- فتحات لإخراج الهواء المختلط البخار في جهاز التعقيم
- فتحات تهوية
- كافة المصامات
- معدات الرص

Mercury-In-glass Thermometer:

- Required
- Calibrated
- Calibration records
- No divided columns
- Easily read
- Reference instrument

الترمومتر الزجاجي الزئبقي

- ضروري
- معاير
- سجلات المعايرة
- لا توجد به أعمدة مقسمة
- يسهل قراءته
- يعد أداه يمكن الرجوع إليها

§113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*–(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale.

§١١٣,٤٠ المعدات والإجراءات اللازمة

(أ) المعدات والاجراءات الازمة لمعالجة الضغط في البخار داخل أجهزة التعقيم الثابتة-- (١) *استخدام الترمومتر الزجاجي الزئبقي.* يتم تجهيز كل جهاز تعقيم بترمومتر زجاجي زئبقي واحد على الاقل وتكون التقسيمات الموجودة به سهلة القراءة حتى ١°ف ويكون مصمما على نحو بحيث لا تزيد درجة الحرارة به عن ١٧°ف لكل بوصة من المقياس المدرج به (أو درجة حرارة مئوية).

Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy.

يتم فحص الترمومترات للتأكد من مدى دقتها وذلك طبقا لترمومتر يعمل وفق معيار معروف عند تركيبه ثم مرة واحدة كل عام أو بشكل متكرر حسبما تقتضي الضرورة وذلك للتأكد من دقتها

Records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy.

ينبغي وجود سجلات لفحص دقة الترمومترات بحيث يتم فيها تحديد التاريخ والمعيار والطريقة المتبعة والشخص الذي يقوم بالفحص والاختبار. وينبغي أن يحمل كل ترمومتر بطاقة بيانات، أو أي وسيله موضحة أخرى توضح تاريخ أخر مرة تم فيها فحص الترمومتر واختبار دقته.

A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.

ينبغي تصليح أو استبدال أي ترمومتر يوجد به عامود زئبقي مقسم أو يصعب ضبطه قبل استخدام جهاز التحقيم مرة أخرى.

Thermometers shall be installed where they can be accurately and easily read.

ينبغي تركيب الترمومترات في المكان الملائم بحيث يسهل قراءتها بدقة وبسهولة.

The mercury thermometer–not the recorder chart–shall be the reference instrument for indicating the processing temperature.

يكون الترمومتر الزئبقي (وليس بيان التسجيل هو المرجع الاساسي لتحديد درجة حرارة التصنيع.

Temperature Recording Device:

- Required
- Chart graduation maximum
- Scale maximum
- Agree with MIG
- Security
- May be part of TRC

جهاز تسجيل درجة الحرارة:

- مطلوب
- يكون تدريج بيان التسجيل عند الحد الاقصى
- يكون المقياس عند الحد الاقصى
- يتوافق مع الترمومتر الزئبقي (MIG)
- تأمينه
- قد يكون جزءاً من بيان تسجيل درجة الحرارة (TRC)

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device.

(٢)جهاز تسجيل درجة الحرارة. ينبغي تجهيز كل جهاز من أجهزة التعقيم الثابتة بجهاز دقيق لتسجيل درجة الحرارة.

Graduations on the temperature-recording devices shall not exceed 2° F within a range of 10° F of the processing temperature.

لا ينبغي أن تزيد علامات التدريج الموجودة بأجهزة تسجيل الحرارة عن ٢° ف في تراوح قدره ١٠°ف لدرجة حرارة التصنيع.

Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature.

ينبغي ان يشمل كل بيان تسجيل مقياسا تشغيليا لا يزيد عن ٥٥°ف لكل بوصة في تراوح قدره ٢٠°ف لدرجة حرارة التصنيع

The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time.

يتم ضبط بيان المسجل لدرجة الحرارة على نحو بحيث يتوافق بقدر الامكان مع الترمومتر الزجاجي الزئبقي المعروف والدقيق اثناء عملية التصنيع ولا يزيد عنه.

A means of preventing unauthorized changes in adjustment shall be provided.

ينبغي توفير وسيلة يتم بمقتضاها منع التغييرات الغير مصرح بها في عملية الضبط.

The recorder may be combined with the steam controller and may be a recording-controlling instrument.

يمكن دمج جهاز التسجيل مع جهاز مراقبة البخار ليصبح جهازا للتسجيل والمراقبة

Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

ينبغي أن تشتمل أجهزة مراقبة درجات الحرارة التي تعمل بالهواء على أنظمة ترشيح ملائمة للتأكد من الامداد المستمر بالهواء النظيف والجاف.

Pressure Gauge:

- Required
- Scale maximum
- Not emphasized

مقياس الضغط:

- مطلوب
- يكون المقياس المدرج عند الحد الاقصى
- غير مؤكد

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(٣) مقاييس الضغط. ينبغي أن يتم تزويد كل جهاز تعقيم بمقياس للضغط يتم تدريجه في تقسيمات تبلغ ٢ باوند (رطل انجليزي) او أقل.

Steam System Requirements:

- Steam controller
- Piping criteria
- Steam spreader
- Bleeders

متطلبات نظام البخار:

- جهاز مراقبة البخار
- المعايير الخاصة بالانابيب
- جهاز نشر البخار
- فتحات لإخراج الهواء المخالط البخار في جهاز التعقيم

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature.

(٤) جهـــاز مراقـــبة البخار. ينبغي تزويد كل جهاز تعقيم بجهاز أوتوماتيكي لمراقبة البخار وذلك للحفاظ على درجة حرارة جهاز التعقيم.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort.

(٥) مدخـــل الـــبخار. ينبغي أن يكون مدخل الـــبخار الموجـــود في كل جهاز تعقيم كبيرا بشكل كاف وذلك لتوفير البخار المطلوب ليتم تشغيل جهاز التعقيم بالشكل الملائم.

Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent;

قد يدخل البخار إما في الجزء العلوي أو في الجزء السفلي من جهاز التعقيم أية حال ينبغي أن يدخل في الجزء المقابل لفتحة التهوية.

(6) *Crate supports.* Baffle plates shall not be used in the bottom of still retorts.

(٦) دعامات صناديق الشحن. لا ينبغي استخدام عوارض تغيير اتجاه الرياح في الجزء السفلي من أجهزة التعقيم الثابتة.

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort.

(٧) أجهزة نشر البخار. تكون استمراراً لخط مدخل البخار الموجود داخل جهاز التعقيم. وينبغي تزويد أجهزة التعقيم الأفقية الثابتة بأجهزة نشر البخار التي تمد من طول جهاز التعقيم.

For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of this pipe

بالنسبة لأجهزة نشر البخار الموجودة على امتداد الجزء السفلي من جهاز التعقيم، فإن الثقوب ينبغي أن تكون على امتداد الجزء العلوي ٩٠° من الماسورة.

The number of perforations should be such that the total cross-sectional area of the perforations is equal to 11/2 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

ينبغي أن يكون عدد الثقوب على نحو بحيث يبلغ إجمالي مساحة المقطع العرضي للثقوب يساوي مساحة المقطع العرضي لأصغر تحديد في خط دخول البخار ب ١,٥ أو ٢مرة.

(8) *Bleeders.* Bleeders shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time.

(٨) فتحات إخراج الهواء المخالط للبخار. ينبغي أن تبلغ الفتحات ٨/١ بوصة أو أكثر وأن تكون مفتوحة طوال فترة التصنيع بما في ذلك فترة وصول جهاز التعقيم لدرجة الحرارة المطلوبة.

For horizontal still retorts, bleeders shall be located within approximately 1 foot of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top.

بالنسبة لأجهزة التعقيم الأفقية الثابتة، ينبغي تركيب الجهاز بحيث يكون على ارتفاع قدم واحد تقريباً من المواضع الخارجية للحاويات عند كل طرف ممتد من الجزء العلوي من الجهاز، وينبغي إضافة فتحات إخراج أخرى عند مسافة لا تزيد عن ٨ أقدام عن الجزء العلوي.

All bleeders shall be arranged so that the operator can observe that they are functioning properly.

ينبغي ترتيب فتحات الاخراج على نحو بحيث يتأكد من يقوم بالتشغيل من انها تعمل بشكل صحيح.

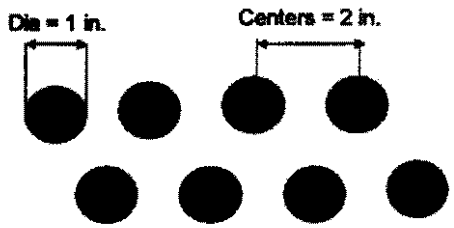
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material.

(٩) معدات الرص ووضع الحاويات. ينبغي أن يتم تصنيع صناديق الشحن والاحواض المسطحة وعربات النقل المكشوفة وما إلى ذلك، الخاصة بحمل الحاويات، من سيور معدنية، أو ألواح معدنية مثقوبة بشكل ملائم أو أي مادة أخرى ملائمة.

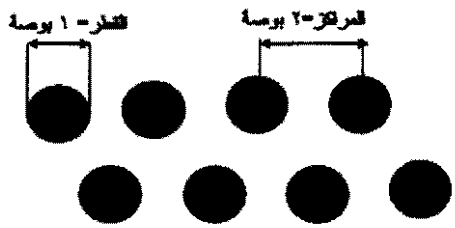
When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers.

عندما يتم استخدام ألواح معدنية مثقوبة للأجزاء السفلية، ينبغي أن يكون قطر الثقوب تقريبا ما يعادل فتحات قطرها ١ بوصة على مراكز تبعد ٢ بوصة.

1-inch holes on 2-inch centers:



فتحات قطرها ١ بوصة على مراكز تبعد ٢ بوصة:



If dividers are used between the layers of containers, they should be perforated as above.

إذا تم استخدام فواصل بين طبقات الحاويات، فانه ينبغي أن يتم ثقبها كما هو مذكور أعلاه.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(١٠) صـــمامات الهواء. ينبغي تجهيز أجهزة الـــتعقيم التي تستخدم الهواء في عملية التبريد بالضـــغط بالصمام الملائم لمنع تسرب الهواء داخل جهاز التعقيم أثناء عملية التصنيع.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(١١) صـمامات الماء. ينبغي تجهيز أجهزة التعقيم التي تستخدم الماء للتبريد بصمام مناسب لمنع تسرب الماء داخل داخل جهاز التعقيم أثناء عملية التصنيع.

Vent System Requirements:

- Valve type
- Piping criteria
- Location

متطلبات نظام فتحات التهوية:

- نوع الصمام
- المعايير الخاصة بالأنابيب
- الموضع

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started.

(١٢) فتحات التهوية. ينبغي أن يكون موضع فتحات التهوية على نحو بحيث يتم إزالة الهواء من جهاز التعقيم قبل بدء توقيت عملية التصنيع.

Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period.

ينبغي التحكم في فتحات التهوية عن طريق استخدام محابس أو أي انواع اخرى من الصمامات التي يتم فتحها كلية للسماح بالتصريف السريع للهواء من جهاز التعقيم أثناء فترة التهوية.

Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain.

لا ينبغي أن تتصل فتحات التهوية بشكل مباشر مع أي نظام تصريف مغلق فإنه اذا تم استخدام الفائض كنوع من التهوية، سيكون هناك نوع من الانقطاع الجوي في الخط قبل ان يتصل بفتحة التصريف المغلقة.

The vent shall be located in that portion of the retort opposite the steam inlet;

ينبغي أن يكون مكان فتحة التهوية في جهاز التعقيم على نحو بحيث تكون في وضع مقابل لمدخل البخار.

PhF Specialists Inc.
Low Acid Canned Foods
CFR 113 Audit

Plant: **Location:** **Date:**

I. Process Design and Registration

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
Does firm have a current FCE number?			
Is location and plant name and information correct?			
Has firm filed products with FDA and do they have valid SID numbers?			
Do filed products, can sizes and sterilizer types correspond to those currently in use for product exported to the US?			
List the process establishment source under comments.			
Are there heat penetration and temperature distribution studies on file?			
Is there a written recommendation for temperature distribution that lists critical factors for each sterilizer type? If yes, detail under comments			
Does the firm maintain documents showing retort diagrams and plumbing? Are changes documented?			
Are temperature distribution studies performed to revalidate performance after changes are made?			

I. Process Design and Registration (Continued)

Item	Acceptable (Yes)	Unacceptable (No)	Comments/Corrective Action
Are there written scheduled processes recommendations for each product that itemize any critical factors? If yes, detail under comments			

II. Process Delivery

A. Critical Factors and Container Integrity			
1.Critical Factors			
Do raw materials, product formulation, particle size, consistency and packing medium correspond to those for which the process was designed and to critical factors listed?			
List filling method: for solids: hand, volumetric, piston, vacuum			
List filling method for liquids: gravity, piston, volumetric			
Is any filling variable listed as a critical factor? Which?			
List monitoring frequency and method for critical fill weight factors.			
Is a record kept for critical fill weight factor? Is it acceptable?			
Are other critical factors required by the process authority or on the filing form monitored and a record kept? List frequency.			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
A. Critical Factors and Container Integrity			
2. Container Integrity			
List type and sizes of containers in use for export to the USA.			
Do container sizes and types correspond to those on the filing form?			
Do temperature distribution studies account for the range of container sizes and styles currently being used?			
List types and number of closing machines.			
Are visual measurements made of closures every 30 minutes and is a record kept?			
Are visual measurements taken and a record kept after closure jams, adjustment, or start up after an extended shut down?			
Are closure teardowns or destructive tests performed at a minimum of every 4 hours and is a record kept?			
List factors measured in destructive tests and method of evaluation.			
Are corrective actions taken and recorded when values do not meet specifications?			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
2. Container Integrity (continued)			
If using glass vacuum closures is there a cold water vacuum check at start up, at changeover, after extended breaks, or jams?			
Have personnel performing closure tests received training?			
Are containers coded on line?			
Does code include firm, product, year, date, and period?			
Is coding period eight hours or less?			
B. Retort Room Operations			
1.Thermal Processing Systems (General)			
Under comments list number of retorts, types of retorts, and manufacturers.			
Do retort systems correspond to filing forms?			
Is each retort equipped with a MIG, readable to 0.5 degrees Centigrade (1 degrees F.)and is the temp. range less than 8 degrees C. (17F.) per CM (inch)?			
Are MIG's calibrated at least annually against a known standard at processing temperature? Are records kept for each MIG showing date?			
Is each retort equipped with a TRC with one-degree C. gradations within 5.5 degrees C. (10 degrees F.)of process temperature?			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
B. Retort Room Operations			
1.Thermal Processing Systems (General)			
Does the TRC have a working scale of not more than 12 degrees C. per Centimeter (55 degrees F. per inch) within 10 degrees C. (20 degrees F.) of process temp?			
Is each retort equipped with a pressure gauge graduated in divisions of 2 lbs. or less?			
Does each retort have an automatic steam controller? List type- electric or pneumatic.			
Is there an automated computerized control system?			
If there is an automated system, describe equipment specs, programming information, how critical factors are controlled, calibration, and validation parameter.			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
B. Retort Room Operations			
1.Thermal Processing Systems (General, Continued)			
Do retort baskets have dividers, racks, or trays? Describe. Were these employed during temperature distribution studies?			
Is orientation of the container in the retort a critical factor? Is it the same as studied for developing the thermal process and temperature distribution?			
B. Retort Room Operations			
2. Procedures			
a. Retort Room			
Are scheduled processes and venting, come up time, or other sterilizer critical factors posted?			
Do scheduled processes correspond to filing forms?			
Are initial temperatures measured and recorded? List interval.			
Are initial temperature readings performed so as to measure average temperature of contents? Is the sample taken from the first container in the first basket? Is the temperature measurement device calibrated against any standard? Frequency			
Is there an easily readable timing device ?			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
B. Retort Room Operations			
2. Procedures			
a. Retort Room			
Is there a system for identifying and segregating retorted and unretorted products? Describe			
How many operators per number of retorts?			
Have operators received any training? Describe.			
Are operators recording critical factors correctly and in real time?			
Is operator using the MIG as the reference temperature?			
Do operators make comparisons between MIG's and TRC's? Does the TRC agree but read no higher than MIG?			
Does the TRC record the correct time of day?			
Is the TRC system protected from unauthorized use or changes?			
Do operators take appropriate action in the case of deviations?			
Observe retort cycle and comment			
B. Retort Room Operations			
2. Procedures			
b. Post Process Container Handling			
Is cooling water chlorinated to a measurable residual and is a record kept? List frequency of testing			

II. Process Delivery

Item	Acceptable (Yes)	Unacceptable (No)	Comments/Corrective Action
B. Retort Room Operations			
2. Procedures			
b. Post Process Container Handling			
Are containers cooled before handling seams? Are containers cooled and dried without further contact from towels, rags or contaminated water?			
Are container handling systems designed to avoid damage, and punctures to seams and containers			
Do cleaning and sanitation protocols exist for container handling systems and are they enforced?			

III. Process Documentation

Is there a written retort record that includes product, code, date, retort number, container, code, CUT, vent and process time and MIG readings?			
Are scheduled process parameters and any other thermal processing critical factors monitored and recorded for each retort cycle?			
Do the records contain errors, omissions, or mistakes that are not initialed or noted?			
Are the written retort records dated and signed by the operator and dated and signed by the supervisor?			

III. Process Documentation

Item	Acceptable (Yes)	Unacceptable (No)	Comments/ Corrective Action
Do the TRC's include the date, retort number, batch, time, operator signature, and reviewer signature?			
Does the firm have a formal program for dealing with process deviations including holding all product processed with a deviation?			
Does a process authority evaluate deviations? Who?			
Does the process authority provide a formal review including evaluation procedures, results of the evaluation and recommended disposition of the product?			
Are records kept showing disposition of suspect product?			
Does the process authority's review also include reviewing records for other critical factors not on the deviation request?			

Auditor:_____ Date:_____

How to Avoid Certain Sanitation Problems

A retrospective of some poor manufacturing techniques I have observed in Egypt

كيفية تفادي بعض مشكلات النظافة

بعض الملاحظات عن تقنيات التصنيع السيئة التي لاحظتها في مصر

Data Base:

- A total of 21 factory visits
- Three were visited twice
- Cairo and Alexandria
- November 1999
- March-April 2000

قاعدة البيانات:

- إجمالي الزيارات كانت لأكثر من ٢١ مصنعا
- تم زيارة ثلاثة مصانع مرتين
- القاهرة والاسكندرية
- نوفمبر ١٩٩٩
- مارس- إبريل ٢٠٠٠

Facility Open to Outside

- Doors open, no fans or strips
- Broken windows
- Torn screens
- Number of observations = 17
- Rank = #1

المصنع مفتوح للخارج

- الأبواب مفتوحة ولا توجد مراوح أو شرائح طويلة
- النوافذ محطمة
- الحواجز السلكية الموجودة على النوافذ ممزقة
- عدد الملاحظات = ١٧
- التصنيف = #١

Trash Stored Inappropriately

- Near processing area
- Next to building
- In processing facility
- Number of observations = 9
- Rank = #2

يتم وضع القمامة بشكل غير صحيح

- بجوار منطقة التصنيع
- بجوار المنشآت
- داخل وحدة التصنيع
- عدد الملاحظات = ٩
- التصنيف = #٢

Animals in or Near Processing Area

- Birds
- Flies
- Rodents
- Dogs
- Bees
- N = 8
- Rank = #3

وجود حيوانات و آفات داخل منطقة التصنيع أو بجوارها

- طيور
- ذباب
- قوارض
- كلاب
- نحل
- عدد الملاحظات = ٨
- التصنيف = #٣

Inappropriate Plant Life

- Weeds, planters, shrubs, potted plants
  - –Inside processing area
  - –Next to building
- Number of observations = 7
- Rank = #4

وجود نباتات غير جيدة وغير ملائمة

- أعشاب وغرسات وشجيرات ونباتات مغروسة في أواني فخارية
  - – داخل منطقة التصنيع
  - – بجوار المنشآت
- عدد الملاحظات = ٧
- التصنيف = #٤

Use of Wooden Implements

- Wood is porous and can be a source of contamination
- Number of observations = 6
- Rank = #5

استخدام أدوات خشبية

- الخشب مسامي ويمكن أن يكون مصدراً للتلوث
- عدد الملاحظات = ٦
- التصنيف = #٥

Dirty Walls and Floors

- Number of observations = 6
- Rank = #5 (tie)

الجدران والأرضيات غير نظيفة

- عدد الملاحظات = ٦
- التصنيف = #٥ (مكرر)

Standing Water

- On floors
- In drains
- Can breed microorganisms
- Number of observations = 5
- Rank = #7

المياه الراكدة

- على الأرضيات
- في المصارف
- يمكن أن تنمو بها الكائنات الدقيقة
- عدد الملاحظات = ٦
- التصنيف = #٧

No Protective Clothing

- Overalls
- Hair restraints
- Shoes
- Line workers
- Quality control
- Management
- Visitors

- N = 5
- Rank = #7 (tie)

عدم إرتداء الملابس الواقية

- الزي الموحد الذي يتم إرتداؤه فوق الملابس لمنع الاتساخ
- أغطية الرأس
- الاحذية
- عدد الملاحظات = ٥
- التصنيف = #٧ (مكرر)
- عمال الخط
- مراقبة الجودة
- الادارة
- الزائرين

Bad Odors

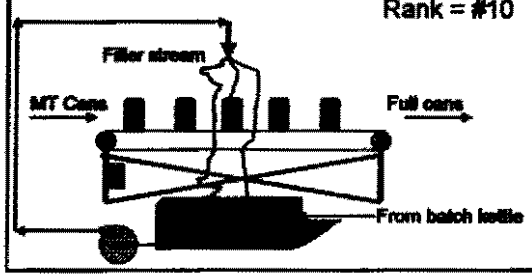
- Odors in the processing area
- Number of observations: 5
- Rank = #7 (tie)

روائح كريهة

- وجود روائح كريهة في منطقة التصنيع
- عدد الملاحظات = ٥
- التصنيف = #٧ (مكرر)

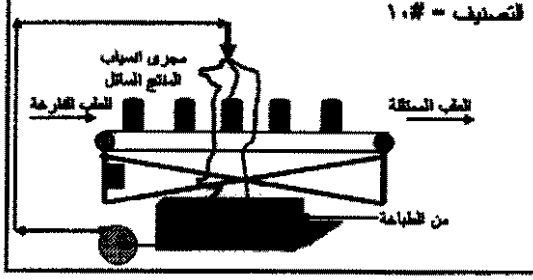
Liquid Product Recovered From Unsanitary Surfaces

N = 4
Rank = #10



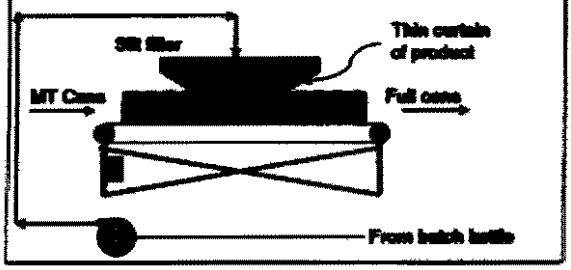
منتج سائل مسترجع من أسطح ملوثة

العدد = ٤
التصنيف = #١٠

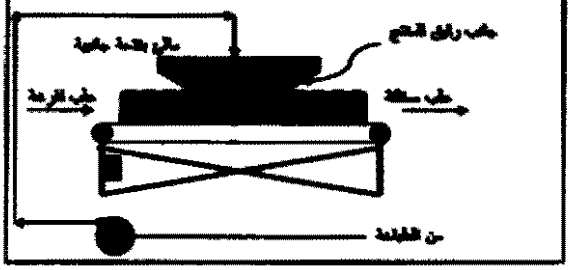


45

How to Avoid Such an Unsanitary Condition

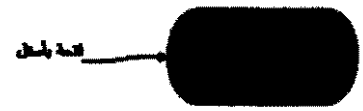


كيفية تفادي تلك الحالة من عدم النظافة



Cross Section of Slit Filler

القطاع العرضي لمالئ بفتحة جانبية



Totes Made of Wood

- Causes abrasion of raw fruit during transit
- Can not be adequately cleaned
- Number of observations = 3
- Rank = #11

صناديق مصنوعة من الخشب

- تتسبب في تآكل الفاكهة غير المصنعة أثناء نقلها
- يصعب تنظيفها بشكل جيد
- عدد الملاحظات = ٣
- التصنيف = #٤

Idle Equipment Dirty From Previous Run

- Causes odors
- Attracts pests
- Makes cleaning more difficult
- Number of observations = 3
- Rank = #11 (tie)

المعدات المتوقفة التي لن يتم تنظيفها من فترة التشغيل السابقة

- تتسبب في وجود روائح كريهة
- تجتذب الآفات
- تصعب من عملية التنظيف
- عدد الملاحظات = ٣
- التصنيف = ١١ (مكرر)

Loose Jewelry

- Number of observations = 3
- Rank = #11 (tie)

الحلي المتدلية

- عدد الملاحظات = ٣
- التصنيف = #١١ (مكرر)

Condensate

- Dripping from unsanitary surface into product tanks
- Number of observations = 3
- Rank = #11 (tie)

ناتج التكثيف

- يسقط من سطح غير نظيف داخل الصهاريج المملوءة بالمنتج
- عدد الملاحظات
- التصنيف = #١١(مكرر)

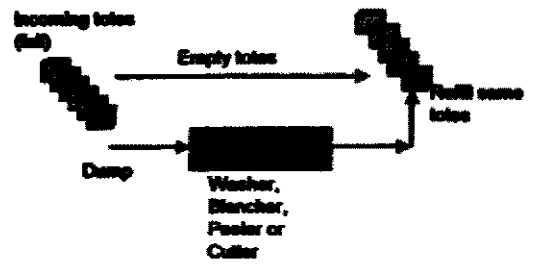
Dirty Totes

- Same totes used for both raw and in-process product
- Number of observations = 2
- Rank = #15

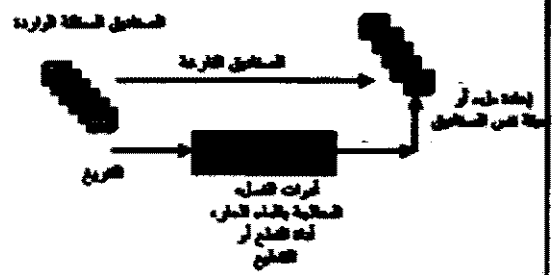
الصناديق غير النظيفة

- هي نفس الصناديق المستخدمة لكل من المنتجات غير المصنعة والمنتجات قيد التصنيع
- عدد الملاحظات = ٢
- التصنيف = #

Example



مثال



Storage of Packaging Material

- Primary packaging materials stored in processing area exposed to splashing
- Number of observations = 2
- Rank = #16

تخزين مواد التعبئة والتغليف

- تكون مواد التعبئة والتغليف المخزونة في منطقة التصنيع عرضة للسقوط والتناثر
- عدد الملاحظات = ٢
- التصنيف = #١٦

Exposed Light Bulbs

- Number of observations = 2
- Rank = #16 (tie)

المصابيح المكشوفة

- عدد الملاحظات = ٢
- التصنيف = #١٦ (مكرر)

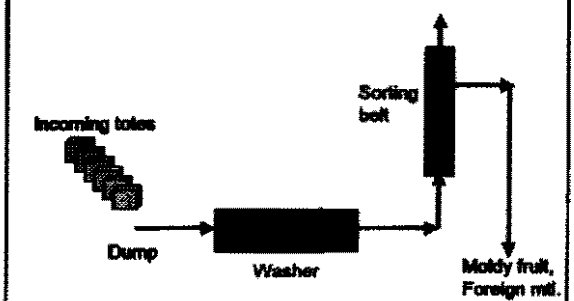
Inadequate Hand Washing

- Dirty hands, fingernails
- Inadequate facilities
  - Towels
  - Soap
  - Hot water
- Number of observations = 1
- Rank = #18

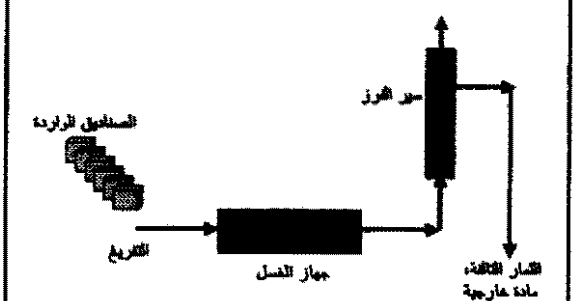
غسل الايدي بطريقة غير صحيحة

- الايدي والاظافر غير نظيفة
- المرافق غير صحية
  - المناشف
  - الصابون
  - المياه الساخنة
- عدد الملاحظات = ١
- التصنيف = #١٨

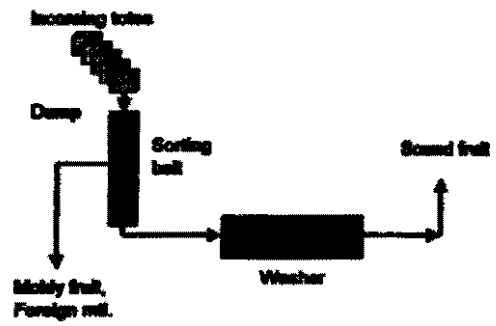
Washing Moldy Fruit



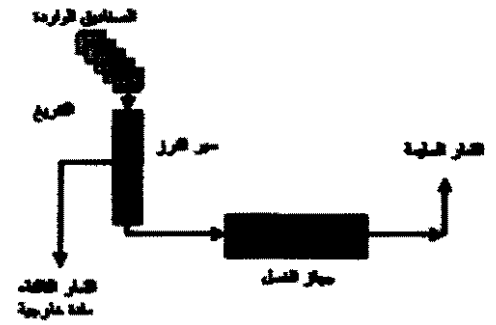
غسل الثمار التالفة أو المتعفنة



Eliminate Moldy Fruit



التخلص من الثمار المتعفنة نهائياً



Too Many to Count

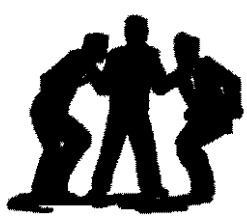
- Rough welds on food contact surfaces
- Threaded fittings on product lines
- Dust/dirt on non-food contact surfaces

هناك الكثير مما يصعب حصره لما يلي:

- وجود خطوط لحام خشنة على الاسطح الملامسة للاغذية
- وجود مسامير ووسائل تثبيت على خط الانتاج
- وجود غبار/اتساخات على الاسطح غير الملامسة للاغذية

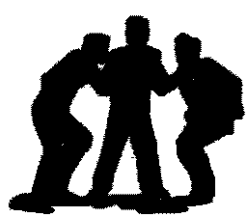
The Biggest Problem

- Inability of management to enforce consistently good sanitation practices



المشكلة الكبرى

- عدم قدرة الإدارة على فرض عملية الالتزام بالاساليب السليمة للصحة العامة من نظافة وتعقيم



Any Sanitation Problems Here?

- Glass bottle near product
- Smoking
- No protective clothing
- Old wooden pallets near line
- Totes very dirty

هل توجد أية مشكلات متعلقة بالنظافة هنا؟

- حاوية زجاجية موجودة بجوار المنتج
- التدخين
- عدم ارتداء الملابس الواقية
- وجود طبالي خشبية قديمة بجوار الخط
- الصناديق شديدة الاتساخ

How to Design Batch Processes

Examples:

How many retorts do I need?

How many batch kettles do I need?

كيفية تصميم عمليات التصنيع على دفعات

أمثلة:

ما هو عدد أجهزة التعقيم التي أحتاجها؟

ما هو عدد الطباخات التي أحتاجها؟

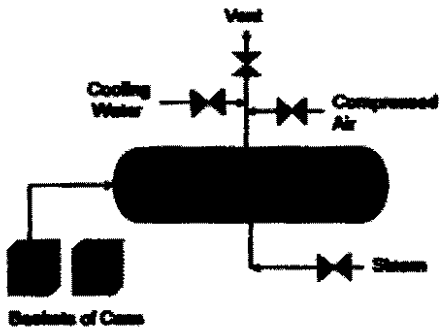
Batch Process

A process in which operations are carried out in discrete steps

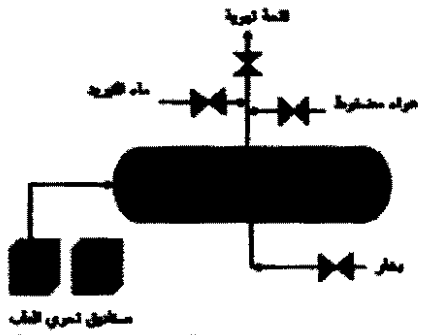
عملية التصنيع على دفعات

هي عملية يتم فيها التشغيل في خطوات منفصلة

Horizontal Still Retort



جهاز تعقيم أفقي ثابت



Line Data

Retort capacity = 3000 cans
Filling speed = 175 cans/minute
Sterilizing time = 60 minutes @121°C
Venting time = 8 minutes after steam on
Cooling time = 20 minutes

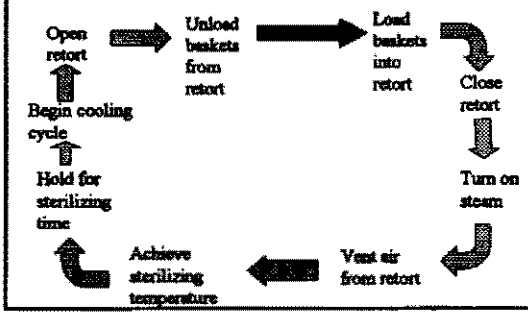
How many retorts are needed?

بيانات خط الانتاج

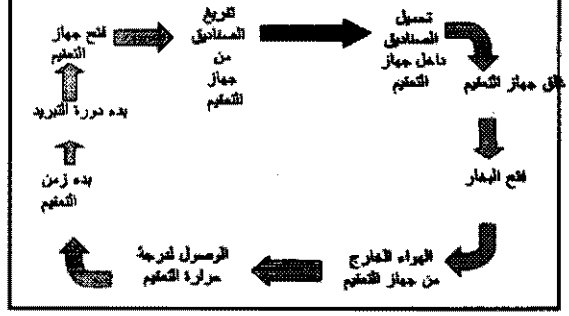
سعة جهاز التعقيم = ٣٠٠٠ علبة
سرعة الملء = ١٧٥ علبة/الدقيقة
زمن التعقيم = ٦٠ دقيقة عند ١٢١°م
زمن التهوية = ٨ دقائق بعد دخول البخار
زمن التبريد = ٢٠ دقيقة

ما هو عدد أجهزة التعقيم المتطلبة

Retort Cycle



دورة جهاز التعقيم



Timing of Each Operation

Operation	Cumulative time (min)
Retort empty	0
Load baskets into retort, close door	5
Open vent, open steam valve	10
Achieve venting requirements, close vent	18
Achieve processing temp. (121°C)	23

توقيت كل عملية

التشغيل	الزمن المجمع (دقيقة)
جهاز التعقيم فارغ	صفر
تحميل الصناديق داخل جهاز التعقيم، ثم غلق الباب	٥
فتح فتحة التهوية، فتح صمام البخار	١٠
تحقيق متطلبات التهوية، غلق فتحة التهوية	١٨
الوصول لدرجة حرارة التصنيع (١٢١°م)	٢٣

Timing (continued)

Operation	Cumulative time (min)
Hold at temp. for processing time	83
Close steam valve, introduce cooling water	88
Complete cooling, close all valves, drain	113
Open retort; remove sterilized baskets	120

التوقيت (تابع)

التشغيل	الزمن المجمع (بالدقيقة)
الثبات عند درجة الحرارة بالنسبة لزمن التصنيع	٨٣
غلق صمام البخار وإدخال ماء التبريد	٨٨
استكمال عملية التبريد وغلق الصمامات وفتح التصريف	١١٣
فتح جهاز التعقيم وإزالة السلال المعقمة	١٢٠

Line Data

Retort capacity = 3000 cans
Filling speed = 175 cans/minute
Time required to complete a retort cycle
=120 minutes

How many retorts are needed?

3000 cans/retort cycle / 120 minutes/retort cycle ⇒ 25 cans/min (one retort)

بيانات الخط

سعة جهاز التعقيم = ٣٠٠٠ علبة
سرعة الملء = ١٧٥ علبة/دقيقة
الزمن المطلوب لاستكمال دورة جهاز التعقيم = ١٢٠ دقيقة

ما هو عدد أجهزة التعقيم المطلوبة؟

٣٠٠٠ علبة/ دورة جهاز التعقيم / ١٢٠ دقيقة/ دورة جهاز التعقيم ⇐ ٢٥ علبة/الدقيقة (جهاز تعقيم واحد)

Line Data (cont.)

3000 cans/retort cycle / 120 minutes/retort cycle ⇒ 25 cans/min (one retort)

One retort can sterilize 25 cans/min.
You need 175 cans/min

175 cans/minute / 25 cans/min-retort ⇒ 7 retorts needed

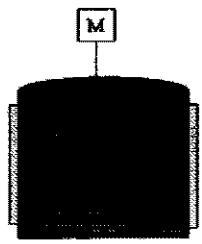
بيانات الخط (تابع)

٣٠٠٠ علبة/ دورة جهاز التعقيم / ١٢٠ دقيقة/ دورة جهاز التعقيم ⇐ ٢٥ علبة/الدقيقة (جهاز تعقيم واحد)

يمكن لجهاز تعقيم واحد أن يعقم ٢٥ علبة/الدقيقة
وأنت تحتاج ١٧٥ علبة/الدقيقة

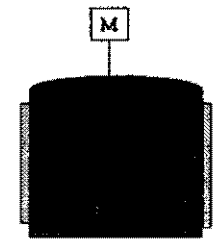
١٧٥ علبة/الدقيقة / ٢٥ علبة/الدقيقة – جهاز التعقيم ⇐ يطلب الأمر ٧ أجهزة من أجهزة التعقيم

Batch Kettle: Pasta Sauce



Capacity = 900 L

الطباخة: صلصة المكرونة



السعة = ٩٠٠ لتر

Formula: Pasta Sauce

Ingredient	%	Kg/batch
Water	42.1	398
Tomatoes, diced	31.0	293
Tomato paste	22.0	208
Olive oil	3.5	33
Salt	1.0	9
Spices	.2	2
Onion, garlic	.2	2

التركيبة الخاصة بصلصة المكرونة

المكونات	%	كجم/الدفعة
ماء	٤٢,١	٣٩٨
طماطم، مقطعة مكعبات	٣١,٠	٢٩٣
معجون الطماطم	٢٢,٠	٢٠٨
زيت زيتون	٣,٥	٣٣
ملح	١,٠	٩
بهارات	٠,٢	٢
بصل، ثوم	٠,٢	٢

Procedure

- Add water
- Add diced tomato
- Add tomato paste
- Add
  - Olive oil, salt,
  - spices, onion,
  - garlic
- Blend
- Perform Q.C. check
- Heat to 85°C
- Drain
- Rinse for next batch

الطريقة

- إضافة الماء
- إضافة الطماطم المقطعة
- إضافة معجون الطماطم
- إضافة ما يلي:
  - زيت زيتون، ملح،
  - بهارات، بصل،
  - ثوم
- تخلط جميع المكونات
- إجراء الفحص الخاص بمراقبة الجودة
- التسخين عند ٨٥°م
- التصريف
- الشطف للدفعة التالية

55

Formula: Pasta Sauce

Ingredient	Kg/batch	Flow rate	Minutes Required
Water	398	20 L/min	20
Dice	293	42 L/min	7
Paste	208	30 L/min	7
Oil	33	15 kg/min	2
Salt	9	9 kg/min	1
Spices	2	2 kg/min	1
O&G	2	2 kg/min	1

التركيبة الخاصة بصلصة المكرونة

المكونات	كجم/الطبخة	معدل التدفق	الدقائق المطلوبة
ماء	٣٩٨	٢٠ لتر/الدقيقة	٢٠
طماطم مقشرة مكعبات	٢٩٣	٤٢ لتر/الدقيقة	٧
معجون الطماطم	٢٠٨	٣٠ لتر/الدقيقة	٧
زيت زيتون	٣٣	١٥ كجم/الدقيقة	٢
ملح	٩	٩ كجم/الدقيقة	١
بهارات	٢	٢ كجم/الدقيقة	١
بصلة فرم	٢	٢ كجم/الدقيقة	١

Formula: Pasta Sauce

Ingredient	Kg/batch	Flow Rate	Minutes Required
Water	398	20 L/min	20
Dice	293	42 L/min	7
Paste	208	30 L/min	7
Oil	33	15 kg/min	2
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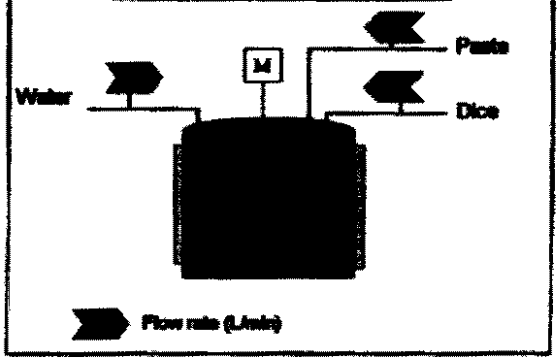
Spices	2	2 kg/min	1
O&G	2	2 kg/min	1

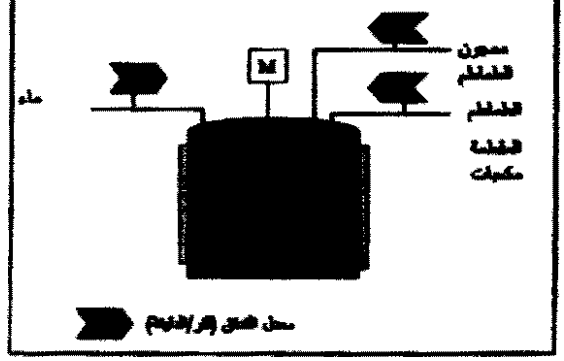
التركيبة الخاصة بصلصة المكرونة

المكونات	كجم/الطبخة	معدل التدفق	الدقائق المطلوبة
ماء	٣٩٨	٢٠ لتر/الدقيقة	٢٠
طماطم مقشرة	٢٩٣	٤٢ لتر/الدقيقة	٧
معجون الطماطم	٢٠٨	٣٠ لتر/الدقيقة	٧
زيت زيتون	٣٣	١٥ كجم/الدقيقة	٢
ملح	٩	٩ كجم/الدقيقة	١
بهارات	٢	٢ كجم/الدقيقة	١
بصلة فرم	٢	٢ كجم/الدقيقة	١

Batch Kettle (cont.)



الطباخة (تابع)



Sequence of Operations

Operation	Time req. (min)
Add ingredients	25
Blend	10
Q.C. check	10
Heat to 85°C	60
Drain	
Rinse	5

تتابع العمليات

العملية	الوقت المتطلب (الدقيقة)
إضافة المكونات	٢٥
الخلط	١٠
إجراء مراقبة الجودة	١٠
التسخين عند ٨٥°م	٦٠
التصفية	
الشطف	٥

Time to Drain Product

Line speed = 175 containers/minute
Container size = 0.5 L
Product demand = 175 X 0.5 = 88 L/min

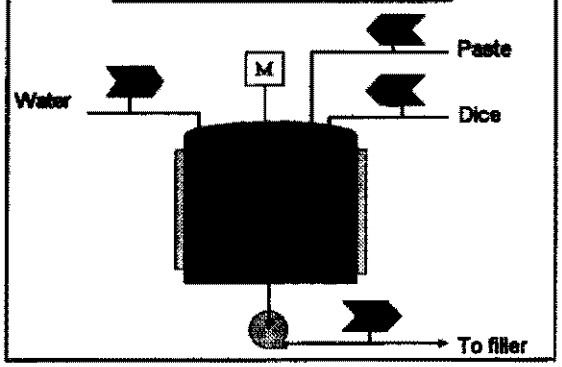
Batch size = 900 L
Time to drain = 900/88 = 10.2 min

الزمن المتطلب لتصفية المنتج

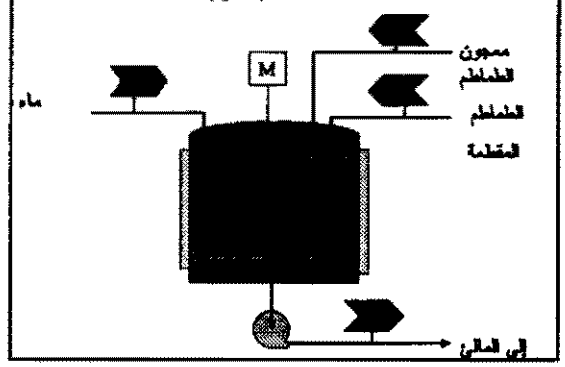
سرعة الخط = ١٧٥ حاوية/الدقيقة
حجم الحاوية = ٠,٥ لتر
يتطلب المنتج = ٠,٥ X١٧٥ = ٨٨ لتر/الدقيقة

حجم الدفعة = ٩٠٠ لتر
وقت التصفية = ٨٨/٩٠٠ = ١٠,٢ دقيقة

Batch Kettle (cont.)



الطباخة (تابع)



Sequence of Operations

Operation	Time req. (min)
Add ingredients	25
Blend	10
Q.C. check	10
Heat to 85°C	60
Drain	10
Rinse	5

Total = 120 min

تتابع العمليات

العملية	الوقت المطلوب (بالدقيقة)
إضافة المكونات	٢٥
الخلط	١٠
إجراء مراقبة الجودة	١٠
التسخين حتى ٨٥°م	٦٠
التصفية	١٠
الشطف	٥

Line Data

Kettle capacity = 900 L
Filling speed = 175 containers/minute
= 88 L/min
Time required to complete a batch cycle
= 120 minutes
How many kettles are needed?

900 L/batch cycle / 120 minutes/batch cycle ⇒ 7.5 L/min (one kettle)

بيانات الخط

سعة الغلاية = ٩٠٠ لتر
سرعة الملء = ١٧٥ علبة/الدقيقة
= ٨٨ لتر/الدقيقة
الزمن المطلوب لاستكمال دورة التصنيع على دفعات
= ١٢٠ دقيقة
ما هو عدد الغلايات المطلوبة؟

٩٠٠ لتر/دورة التصنيع على دفعات / ١٢٠ دقيقة/دورة التصنيع على دفعات ⇐ ٧,٥ لتر/الدقيقة (غلاية واحدة)

Line Data (cont.)

900 L/batch cycle / 120 minutes/batch cycle ⇒ 7.5 L/min (one kettle)

One kettle can produce 7.5 L/min.
You need 88 L/min

88 L/minute / 7.5 L/min-kettle ⇒ 11.7 kettles needed

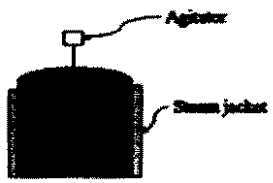
بيانات الخط (تابع)

٩٠٠ لتر/دورة التصنيع على دفعات / ١٢٠ دقيقة/دورة التصنيع على دفعات ⇐ ٧,٥ لتر/الدقيقة (غلاية واحدة)

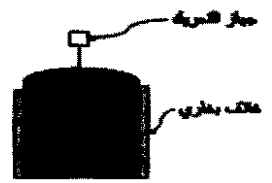
يمكن لغلاية واحدة أن تنتج ٧,٥ لتر/الدقيقة
وأنت تحتاج ٨٨ لتر/الدقيقة

٨٨ لتر/الدقيقة / ٧,٥ لتر/الدقيقة – الغلاية ⇐ يطلب الآخر ١١,٧ غلاية

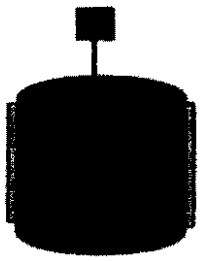
How to Estimate Heating Times for Liquid Foods



كيفية تقدير أزمنة تسخين الاغذية السائلة



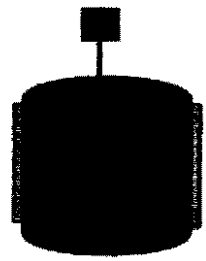
Heating Tank



Properties:

-Liquid volume
-Agitator speed
-Area of steam jacket
-Max. pressure in jacket

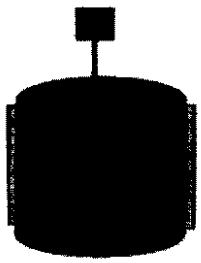
صهاريج التسخين



الخواص:

- حجم السائل
- سرعة جهاز التحريك
- مساحة الغلاف البخاري
- الحد الاقصى من الضغط داخل الغلاف

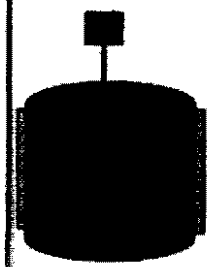
Heating Time



Depends on:

-Initial temperature
-Final temperature
-Steam temperature
-Properties of the liquid

زمن التسخين



يعتمد على:

- درجة الحرارة البدئية
- درجة الحرارة النهائية
- درجة حرارة البخار
- خواص السائل

Properties of the Liquid

- Density (or specific gravity)
- Viscosity
- Heat capacity
- Thermal conductivity

خواص السائل

- الكثافة (أو جاذبية معينة)
- اللزوجة
- السعة الحرارية
- التوصيل الحراري

Viscosity

- The resistance to flow

–Note: This same resistance to flow also provides resistance to heat and mass transfer

اللزوجة

- مقاومة الانسياب

ملحوظة: إن نفس المقاومة الخاصة بالانسياب توفر كذلك مقاومة لنقل الحرارة والكميات الكبيرة

Viscosity Coefficient

An experimentally determined number used in fluid mechanics to account for the effects of viscosity

Units: Centipoise or Millipascal seconds (gm/cm-sec)

معامل اللزوجة

هو رقم يحدد اختبارياً يستخدم في ميكانيكيات السوائل لتوضيح تأثير اللزوجة

الوحدات: سنتي بويز أو ملليباسكال/الثانية (جم/سم – الثانية)

CB

Approximate Viscosity Coefficient of Selected Compounds

Compound	Viscosity (Centipoise)
Ether	0.1
Water	1
Kerosene	10
Motor Oil (SAE 10)	100
Glycerine	1,000
Corn Syrup	10,000
Molasses	100,000

معامل اللزوجة بالتقريب فيما يتعلق بالمركبات المتكافئة التالية

المركب	اللزوجة (بنقي عديل)
أثير	٠,١
ماء	١
كيروسين	١٠
زيت موتور (SAE 10)	١٠٠
جليسرين	١,٠٠٠
شراب الذرة	١٠,٠٠٠
عسل أسود	١٠٠,٠٠٠

Which is Thicker?

- Honey, or
- Mayonnaise

أي مما يلي أغلظ في القوام؟

- العسل، أم
- المايونيز

Properties of the Liquid

- Density (or specific gravity)
- Viscosity
- Heat capacity
- Thermal conductivity

خواص السائل

- الكثافة (أو جاذبية معينة)
- اللزوجة
- السعة الحرارية
- التوصيل الحراري

Heat Capacity

The amount of heat (in calories) required to raise the temperature of 1 gram of a substance by 1°C.

Units = calories/gm-°C

Cp

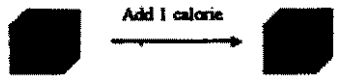
السعة الحرارية

كمية الحرارة (بالسعرات الحرارية) المتطلبة لرفع درجة حرارة ١ جم من المادة بحوالي ١°م

الوحدات = سعرات حرارية/جم- °م

Cp

Heat Capacity

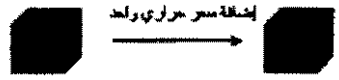


One gm water @ 25°C

One gm water @ 26°C

Cp = 1 cal/gm-°C

السعة الحرارية



جرام واحد من الماء عند ٢٦°م

جرام واحد من الماء عند ٢٥°م

Cp = ١ سعر حراري/جم - °م

Heat Capacities of Selected Foods

Food	% Water	Cp
Water	100	1.0
Potato soup	88	0.94
Potatoes	75	0.81
Peas, dried	14	0.44
Soy oil	0	0.40

السعة الحرارية للأغذية المنتقاة أدناه

المنتج الغذائي	الماء %	CP
ماء	١٠٠	١,٠
مرق الشمندر	٨٨	٠,٩٤
بطاطس	٧٥	٠,١٨
بازلاء مجففة	١٤	٠,٤٤
زيت الصويا	٠	٠,٤٠

Properties of the Liquid

- Density (or specific gravity)
- Viscosity
- Heat capacity
- Thermal conductivity

خواص السائل

- الكثافة (أو جاذبية معينة)
- اللزوجة
- السعة الحرارية
- التوصيل الحراري

Thermal Conductivity

A measure of the ability of a substance to conduct heat

Units = calories/sec-cm-^{o}C

التوصيل الحراري

هو قياس قدرة المادة على توصيل الحرارة

الوحدات = سعرات حرارية/الثانية – سم – °م

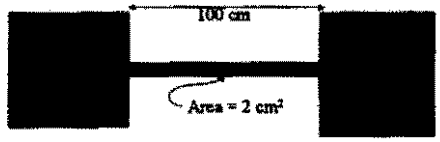
Thermal Conductivity of Selected Materials

Material	Thermal Conductivity (calories/sec-cm-^{o}C)
Peanut oil	0.4×10^{-3}
Vegetables (avg.)	1×10^{-3}
Meats (avg.)	1.2×10^{-3}
Water	1.3×10^{-3}
Stainless steel	39×10^{-3}
Copper	951×10^{-3}

التوصيل الحراري للمواد المنتقاة التالية

المادة	التوصيل الحراري (السعرات الحرارية/الثانية-سم- °م
زيت الفول السوداني	$٠,٤ \times ١٠^{-٣}$
الخضروات (بالوسط)	١×١٠^{-٣}
اللحوم (بالوسط)	$١,٢ \times ١٠^{-٣}$
الماء	$١,٣ \times ١٠^{-٣}$
الفولاذ الذي لا يصدأ	٣٩×١٠^{-٣}
النحاس	٩٥١×١٠^{-٣}

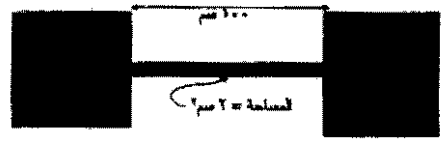
Thermal Conductivity



Rate of heat transfer (calories/sec) = $q = kA(T_1-T_2)/L$

Rate = $q = .039*2(121-25)/100 = 0.073$ cal/sec

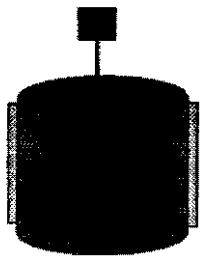
التوصيل الحراري



معدل النقل الحراري (سعرات حرارية/الثانية) : $q = kA(T_1-T_2)/L$

المعدل هو: $q = .039*2(121-25)/100 = 0.073$ cal/sec

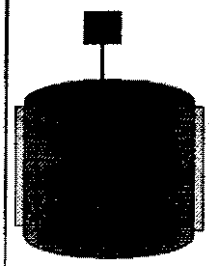
Heating Time



Depends on:

-Initial temperature
-Final temperature
-Steam temperature
-Properties of the liquid
-Liquid volume
-Agitator speed
-Area of steam jacket
-Max. pressure in jacket

زمن التسخين



يعتمد على:

- درجة الحرارة المبدئية
- درجة الحرارة النهائية
- درجة حرارة البخار
- خواص البخار
- حجم السائل
- سرعة جهاز التحريك
- مساحة الغلاف البخاري
- الحد الاقصى للضغط في الغلاف

Heating Time

Depends on:

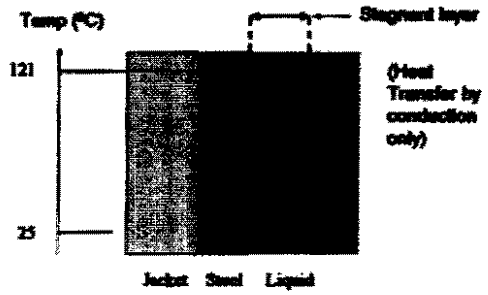
-Initial temperature	25°C
-Final temperature	85°C
-Steam temperature	121°C
-Properties of the liquid	Water
-Liquid volume	900 L
-Agitator speed	22 rev/min
-Area of steam jacket	2 M^2

زمن التسخين

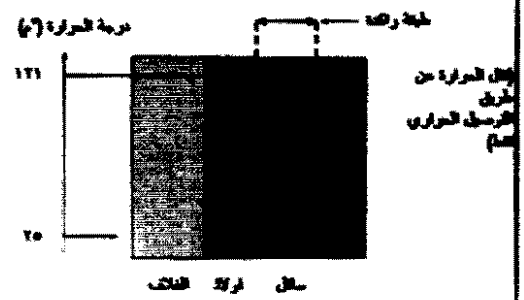
يعتمد على

درجة الحرارة المبدئية	٢٥°م
درجة الحرارة النهائية	٨٥°م
درجة حرارة البخار	١٢١°م
خواص السائل	ماء
حجم السائل	٩٠٠ لتر
سرعة الجهاز المحرك	٢٢ دورة /الدقيقة
مساحة الغلاف البخاري	٢م٢

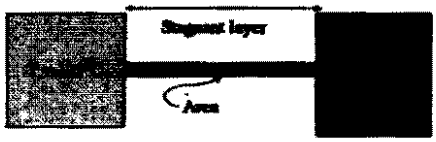
Crossection of Tank



المقطع العرضي للصهريج

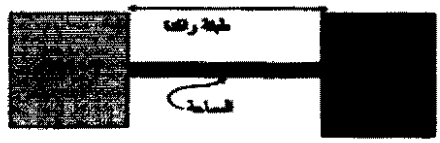


Similarity to Conductivity



Rate of heat transfer (calories/sec) = $q = kA(T_1-T_2)/L$

التشابه مع التوصيل الحراري



معدل النقل الحراري (سعرات حرارية/الثانية) $q = kA(T_1-T_2)/L$

What do we know?

Rate of heat transfer = $q = kA(T_1-T_2)/L$

- k depends on fluid
- Area = A = $2M^2$ = 20,000 cm^2
- T_1 = 121°C
- T_2 = 25°C, but varies with time
- L is unknown but depends on
  - Viscosity
  - Agitator speed
  - Density
  - Heat Capacity

ما الذي نعرفه؟

معدل النقل الحراري = $q = kA(T_1-T_2)/L$

K تعتمد على السائل
المساحة = ٢م^2 = ٢٠,٠٠٠سم^2
T_1 = ١٢١°م
T_2 = ٢٥ °م لكنها تختلف مع الوقت
L غير معروفة لكنها تعتمد على
اللزوجة
سرعة جهاز التحريك
الكثافة
السعة الحرارية

What do we Know?

Rate of heat transfer = $q = kA(T_1-T_2)/L$

or:
$q = k/L*A(T_1-T_2)$

or:
$q = UA(T_1-T_2)$

Where $U = k/L$
= heat transfer coefficient

ما الذي نعرفه؟

معدل النقل الحراري = $q = kA(T_1-T_2)/L$

أو:
$q = k/L*A(T_1-T_2)$

أو:
$q = UA(T_1-T_2)$

حيث تكون: $U = k/L$
= معامل النقل الحراري

Selected Heat Transfer Coefficients

Condition	U x 10^3 (cal/sec-cm^2-°C)
Gasses	0.3 to 3.0
Viscous liquids	1.4 to 13.6
Water	13.6 to 136
Boiling water	40 to 525
Condensing steam	135 to 407

بعض عوامل النقل الحراري المنتقاة

الحالة	U X 10^3 (cal/sec-cm2-°C)
غازات	٠,٣ الى ٣,٠
سوائل لزجة	١,٤ الى ١٣,٦
ماء	١٣,٦ الى ١٣٦
ماء مغلي	٤٠ الى ٥٢٥
بخار التكثيف	١٣٥ الى ٤٠٧

The variations in the values of heat transfer coefficients means you can not look up a value in a book. It must be measured.

إن اختلاف مقادير عوامل النقل الحراري يعني انه لا يمكنك البحث عن أي مقدار في كتاب ما فالمقدار ينبغي قياسه.

What do we Know?

Rate of heat transfer = $q = UA(T_1-T_2)$

Varies over the heating time since the water temperature (T2) increases with time

ما الذي نعرفه؟

معدل النقل الحراري - $q = UA(T_1-T_2)$

يتنوع طبقاً لزمن التسخين نظراً لأن درجة حرارة الماء (T2)تزيد مع الوقت

What Else do we Know?

The total heat load is the amount of heat required to raise the temperature of the water from 25 to 85°C

$Q = MCp(T_{final}-T_{initial}) = 900x1000x1x1(85-25)$

$= 54,000$ calories

ماذا نعرف أيضاً؟

يكون الحمل الحراري الكلي هو كمية الحرارة المتطلبة لرفع درجة حرارة الماء من ٢٥ الى ٨٥° م

$Q = MCp(T_{final}-T_{initial}) = 900x1000x1x1(85-25)$

$= 54,000$ calories

Anything Else?

The heat transfer coefficient (U) is not known with precision.

هل هناك شئ آخر؟

لا يعرف معامل النقل الحراري (U) بشكل دقيق

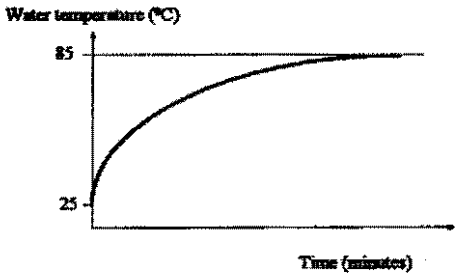
Two Problems

- The rate of heat transfer is reduced as the water temperature approaches the target
- The heat transfer coefficient (U) is only an approximation

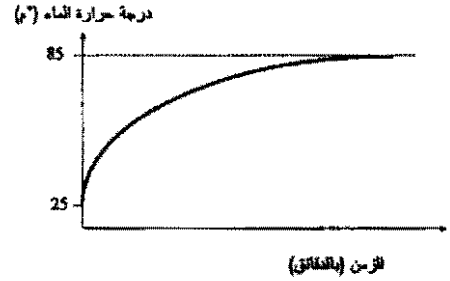
ثمة مشكلتين

- يقل معدل النقل الحراري عندما تقترب درجة حرارة الماء من الدرجة المطلوبة
- يكون معامل النقل الحراري (U) بالتقريب فقط

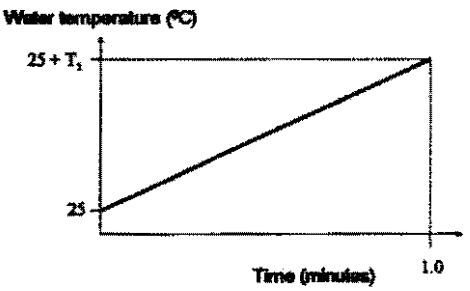
Temperature vs. Time



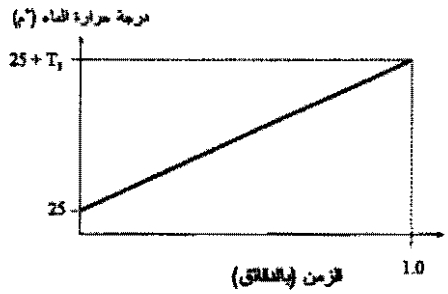
درجة الحرارة مقابل الزمن



Temperature vs. Time



درجة الحرارة مقابل الزمن



HEAT TRANSFER CALCULATIONS
AGITATED TANK WITH STEAM JACKET

1. ENTER DATA FROM A TEST RUN WITH SMALL TEMPERATURE RISE KEEPING HEAT TRANSFER COEFFICIENT AT 0.135 CAL/CM^2-SEC-^{0}C

2. SET THE TIME INTERVAL SO THAT AT LEAST 100 INTERVALS ELAPSE DURING TEST RUN (EXAMPLE: FOR A TEST RUN OF 10 MINUTES THE CALCULATION INTERVAL SHOULD BE 0.1 MINUTE.)

3. SEE HOW THE ACTUAL TIME OF HEATING COMPARES TO THE CALCULATED TIME. CHANGE THE VALUE OF THE HEAT TRANSFER COEFFICIENT BY TRIAL AND ERROR UNTIL CALCULATED VALUE AGREES WITH ACTUAL.

4. YOU CAN NOW PREDICT HEATING TIMES FOR THE SAME TANK, SIMILAR FLUIDS AND THE SAME AGITATOR SPEED.

HEAT TRANSFER COEFFICIENT	0.135	CALORIES/CM^2-SEC-^{0}C	MCp =
AREA OF THE HEATING JACKET	81	SQUARE METERS	UA /2=
STEAM TEMPERATURE	121	^{0}C	
STARTING TEMPERATURE	25	^{0}C	
FINISHED TEMPERATURE DESIRED	85	^{0}C	
HEAT CAPACITY OF FLUID	1	CALORIES/GM-^{0}C	
VOLUME OF FLUID	8000	LITERS	
DENSITY OF FLUID	1	GM/CM^3	
TIME INTERVAL FOR CALCULATION	1	MINUTE	

HEATING TIME (INTERVALS)	LIQUID TEMPERATURE (^{0}C)
0	25
1	25.7
2	26.3
3	27.0
4	27.6
5	28.2
6	28.9
7	29.5
8	30.1
9	30.7
10	31.4
11	32.0
12	32.6
13	33.2
14	33.8
15	34.4
16	35.0
17	35.6
18	36.1
19	36.7
20	37.3
21	37.9

22	38.4
23	39.0
24	39.6
25	40.1
26	40.7
27	41.2
28	41.8
29	42.3
30	42.9
31	43.4
32	43.9
33	44.4
34	45.0
35	45.5
36	46.0
37	46.5
38	47.0
39	47.5
40	48.0
41	48.5
42	49.0
43	49.5
44	50.0
45	50.5
46	51.0
47	51.5
48	51.9
49	52.4
50	52.9
51	53.3
52	53.8
53	54.3
54	54.7
55	55.2
56	55.6
57	56.1
58	56.5
59	56.9
60	57.4
61	57.8
62	58.2
63	58.7
64	59.1
65	59.5
66	59.9
67	60.4
68	60.8
69	61.2
70	61.6
71	62.0
72	62.4
73	62.8
74	63.2
75	63.6
76	64.0

77	64.4
78	64.8
79	65.2
80	65.5
81	65.9
82	66.3
83	66.7
84	67.0
85	67.4
86	67.8
87	68.1
88	68.5
89	68.9
90	69.2
91	69.6
92	69.9
93	70.3
94	70.6
95	71.0
96	71.3
97	71.6
98	72.0
99	72.3
100	72.6
101	73.0
102	73.3
103	73.6
104	74.0
105	74.3
106	74.6

Capital Cost:

- Includes cost of:
  - Purchasing equipment
  - Installing equipment
  - Housing equipment
  - Providing utilities for equipment
  - Providing ancillary facilities (eg. offices)

التكلفة الرأسمالية للمصنع

- تتضمن تكلفة ما يلي:
  - شراء معدات
  - تركيب معدات
  - تجهيز المنشأت
  - توفير المرافق للمعدات
  - توفير المرافق الانشائية (مثل المكاتب)

Preliminary Capital Estimates

- To determine feasibility
- To obtain financing
- To screen alternatives

تقديرات الاولية للتكلفة الرأسمالية للمصنع

- تحديد الجدوى
- الحصول على التمويل اللازم
- توضيح البدائل

How to Estimate Capital Costs

- Determine the cost of each part
- Add the cost of installation
- Add direct and indirect costs

كيفية تقدير التكاليف الرأسمالية للمصنع

- تحديد تكلفة كل جزء
- إضافة تكلفة التركيب
- إضافة التكاليف المباشرة وغير المباشرة

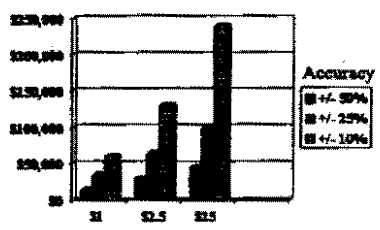
Accuracy of Estimate

- Accuracy = f (information)
  - The more information required:
    - –The estimate itself:
      - »Costs more and
      - »Takes longer

دقة التقدير

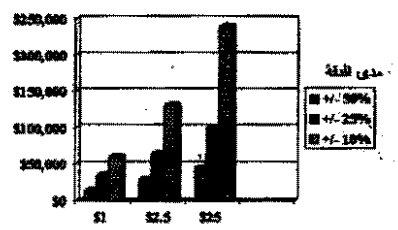
- الدقة – المعلومات
- كلما كان هناك مزيد من المعلومات المتطلبة:
  - –كلما زادت تكلفة
  - »التقدير نفسه
  - »وكلما استغرق الامر مدة اطول

Costs of Making an Estimate



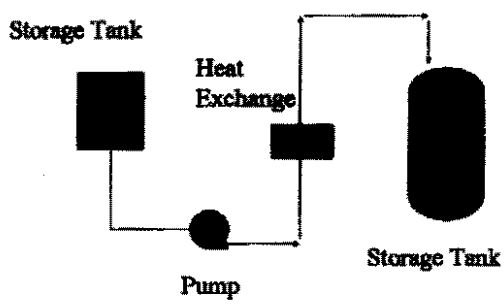
Cost of Project ($MM)

تكاليف إجراء التقدير

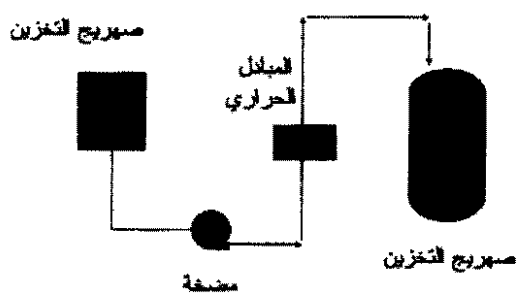


تكلفة المشروع (بالمليون دولار)

A Simple Process



عملية بسيطة



Cost of Major Items

• Tank (T-1)	$35,000
• Pump (P-1)	$8,500
• Heat Exch. (H-1)	$45,000
• Tank (T-2)	$100,000
Total	$188,500

تكلفة الأجزاء الرئيسية

• المستودع (الاول)	٣٥,٠٠٠ دولار
• المضخة (P-1)	٨,٥٠٠ دولار
• المبادل الحراري (H-1)	٤٥,٠٠٠ دولار
• المستودع (الثاني)	١٠٠,٠٠٠ دولار
الاجمالي	١٨٨,٥٠٠ دولار

Main Plant Items: MPI

- Defined:
  - The major items in a process
- In this example cost of MPI:
  - $188,500; delivered

أجزاء المصنع الرئيسية

- تعرف بأنها:
  - الاجزاء الرئيسية في عملية التصنيع
- في هذا المثال تكون تكلفة أجزاء المصنع الرئيسية:
  - ١٨٨,٥٠٠ دولار التي تم تسليمها

But What About...

- Site preparation
- Installation
- Piping
- Insulation
- Instrument-ation
- Electrical
- Other utilities
- Buildings

لكن ماذا عن ...

- إعداد الموقع
- التركيبات
- مد المواسير
- العزل
- استخدام الادوات
- التركيبات الكهربائية
- المرافق الاخرى
- المنشآت

Total Fixed Capital Costs

- MPI + Ancillary equipment, or
- (MPI) X (Factor)

إجمالي التكاليف الرأسمالية للمصنع الثابتة

- أجزاء المصنع الرئيسية + المعدات الاضافية، أو
- (أجزاء المصنع الرئيسية) X (المعامل)

Total Fixed Capital Costs:

Fixed capital = MPI X Factor

Fixed capital = $188,500 X 3

Fixed capital = $565,500

Ancillary equipment cost = $377,000

إجمالي التكاليف الرأسمالية للمصنع الثابتة

التكلفة الثابتة = أجزاء المصنع الرأسمالية للمصنع X المعامل

التكلفة الثابتة = ١٨٨,٥٠٠ X ٣

التكلفة الثابتة = ٥٦٥,٥٠٠ دولار

تكلفة المعدات الاضافية = ٣٧٧,٠٠٠ دولار

The Factor Depends On:

- Size (or capacity)
- Materials of construction
- Operating pressure

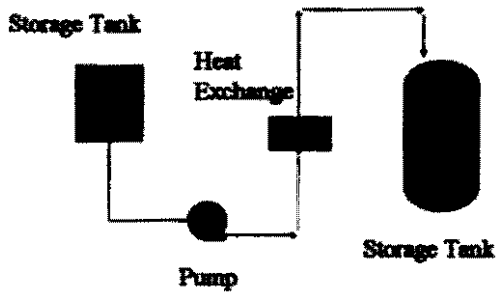
Each is related to cost of MPI

يعتمد المعامل على ما يلي:

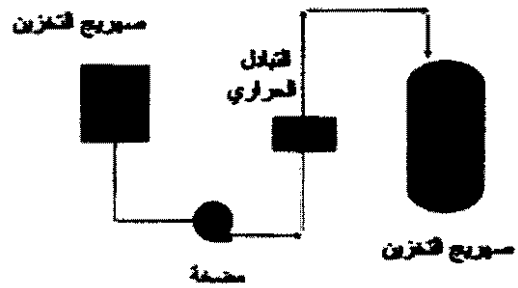
- الحجم (أو السعة)
- مواد الانشاء
- ضغط التشغيل

كل مما سبق يتعلق بتكلفة أجزاء المصنع الرئيسية

Another Look



رؤية أخرى



Materials of Construction

	Stainless	Carbon
T-1	$35M	$10M
P-1	$8.5M	$2M
H-1	$45M	$15M
T-2	$100M	$30M
Totals	$188M	$57M

مواد الانشاء

	ستانلس ستيل	حديد كربوني
T-1	٣٥ مليون دولار	١٠ مليون دولار
P-1	٨.٥ مليون دولار	٢ مليون دولار
H-1	٤٥ مليون دولار	١٥ مليون دولار
T-2	١٠٠ مليون دولار	٣٠ مليون دولار
الاجمالي	١٨٨ مليون دولار	٥٧ مليون دولار

But What About...

- Site preparation
- Installation
- Piping
- Insulation
- Instrumentation
- Electrical
- Other utilities
- Buildings

لكن ماذا عن...

- إعداد الموقع
- التركيبات
- مد المواسير
- العزل
- استخدام الادوات
- التركيبات الكهربائية
- المرافق الاخرى
- المنشآت

Total Fixed Capital Costs:

(Stainless)

Fixed capital = MPI X Factor

Fixed capital = $188,500 X 3

Fixed capital = $565,500

Ancillary equipment cost = $377,000

إجمالي التكاليف الرأسمالية للمصنع الثابتة

(ستانلس ستيل)

التكلفة الثابتة = أجزاء المصنع الرأسمالية للمصنع X المعامل

التكلفة الثابتة = ١٨٨,٥٠٠ X ٣

التكلفة الثابتة = ٥٦٥,٥٠٠ دولار

تكلفة المعدات الاضافية = ٣٧٧,٠٠٠ دولار

Total Fixed Capital Costs:

(Carbon Steel)

Fixed capital = MPI X Factor

Ancillary equip. cost = $377M

Fixed capital = $57M + $377M

Factor = 7.5

إجمالي التكاليف الرأسمالية للمصنع الثابتة

(حديد كربوني)

التكلفة الثابتة = أجزاء المصنع الرئيسية X المعامل

تكلفة المعدات الاضافية = ٣٧٧ مليون دولار

التكلفة الرأسمالية للمصنع الثابتة = ٥٧ مليون دولار + ٣٧٧ مليون دولار

المعامل = ٧,٥

Total Fixed Capital Costs:

Fixed capital = MPI X Factor

As the unit cost of equipment increases the factor decreases

إجمالي التكاليف الرأسمالية للمصنع الثابتة

التكلفة الرأسمالية للمصنع الثابتة = أجزاء المصنع الرئيسية X المعامل

كلما زادت تكلفة الوحدة من المعدات كلما قل المعامل

Estimating Techniques

- "Nothing succeeds like excess."

–Oscar Wild

تقنيات التقدير

- " التفاني في العمل هو أفضل طريق للنجاح"

–أوسكار وايلد

Refined Factor Method

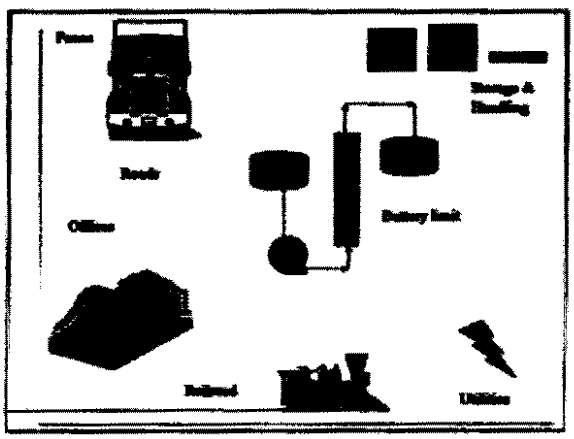
Presumes that the factors vary with the average unit cost of MPI

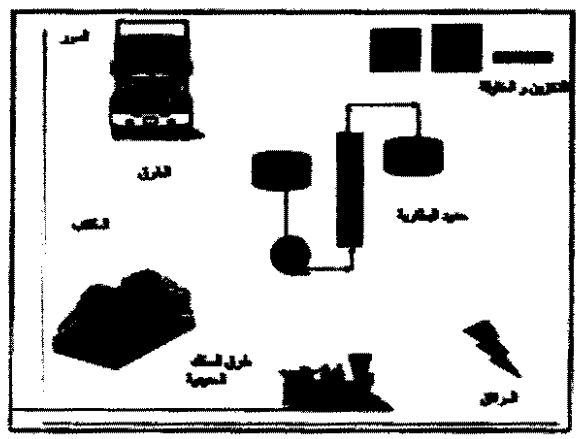
Also, each part of the factory has its own factor

طريقة المعامل الدقيقة

تفترض أن المعامل يتنوع طبقا لمتوسط تكلفة الوحدة من اجزاء المصنع الرئيسية

كذلك، يكون لكل جزء من المصنع المعامل الخاص به





RATIO FACTORS FOR ESTIMATING BATTERY-LIMIT COSTS

		Range of Factors as Percent of Basic Equipment						
		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $99M	OVER $99M
BASIC EQUIPMENT: Delivered to site, excluding sales tax	M.P.I. (Main Plant Items):	X	X	X	X	X	X	X
	M.U.E. (Miscellaneous unlisted items):							
	Early flowsheet stage	20 to 10% of M.P.I.'s in all categories						
	Scope of work well defined	10 to 1% of M.P.I.'s in all categories						
	Note: Top of ranges: Complicated processes; many process steps							
	Bottom of ranges: Simple processes; few process steps							
BASIC EQUIPMENT = M P I + M U E		100	100	100	100	100	100	100
FIELD ERECTION OF BASIC EQUIPMENT	High percentage of equipment involving high field labor	23/18	21/17	19/16	18/15	17/14	16/13	15/13
	AVERAGE (Mild steel equipment)	18/12	17/11	16/11	15/10	14/9	13/8	13/8
	High percentage of corrosion materials and other high unit cost equipment involving little field erection	12/7	11/7	11/6	10/5	9/5	8/5	8/5

		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $66M	OVER $66M
EQUIPMENT FOUNDATIONS AND STRUCTURAL SUPPORTS	HIGH - Predominance of compressors or mild steel equipment requiring heavy foundations			17/12	15/10	14/9	12/8	11/8
	AVERAGE - Mild steel fabricated equipment			13/7	11/6	10/5	8/4	7/3
	LOW/AVERAGE - Predominance of alloy and other high unit price fabricated equipment	7/3	7/3	9/3	8/3	7/3	6/2	5/1.2
	LOW - Equipment more-or-less standing on the floor	5/0	4/0	3/0	3/0	2/0	2/0	1/0
PIPING (includes ductwork excludes insulation	HIGH-Gases and liquids, petrochemicals, BBplants with substantial ductwork	105/65	90/58	80/48	70/40	58/34	50/30	42/25
	AVERAGE FOR CHEMICAL PLANTS; Liquids	65/33	58/27	48/22	40/16	34/12	30/10	25/9
	LIQUIDS AND SOLIDS	33/13	27/10	22/8	16/6	12/5	10/4	9/3
	LOW - Solids	13/5	10/4	8/3	6/2	5/1	4/0	3/0
INSULATION OF EQUIPMENT ONLY	VERY HIGH - Substantial mild steel equipment requiring lagging and very low temperatures	13/10	12/9	10/7	9/6	8/5	7/5	6/4
	HIGH - Substantial equipment requiring lagging and high temperatures (petrochemicals)	10/17	9/6	8/5	7/4	6/3	5/3	5/3
	AVERAGE FOR CHEMICAL PLANTS	8/3	7/3	6/2	5/2	4/1	3/1	2/1
	LOW	4/0	3/0	2/0	2/0	2/0	1/0	1/0
INSULATION OF PIPING ONLY	VERY HIGH - Substantial mild steel piping requiring lagging and very low temperatures	13/10	12/9	10/7	9/6	8/5	7/5	6/4
	HIGH - substantial piping requiring lagging and high temperatures	18/14	15/12	13/10	11/8	9/6	7/4	4/3
	AVERAGE FOR CHEMICAL PLANTS	16/12	14/10	12/8	10/6	8/4	6/2	4/2
	LOW	14/8	12/6	10/5	8/4	6/3	4/2	2/1

		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($\times 10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $80M	OVER $80M
ALL ELECTRICAL except building lighting and instrumentation	Plants with mild steel equipment, heavy drives, solids	26/17	23/15	20/13	14/9	14/8.5	12/7	10/6
	Plants with alloy or high unit-cost equipment, chemical and petrochemical plants	18/10	16/9	13/7	11/6	9/5	7/4	6/3
	NOTE: Above figures include 1 to 3% for B/L outside lighting which is not covered in Building Services							
INSTRUMENTATION	Substantial instrumentation, central control panels,petrochemicals		59/31	46/24	37/18	29/13	23/10	18/7
	MISCELLANEOUS CHEMICAL PLANTS		32/13	26/10	20/7	15/5	11/3	8/2
	Little instrumentation, solids		21/8	17/7	13/5	10/3	7/2	5/1
	NOTE: Total instrumentation cost does not vary a great deal with size and hence is not readily calculated as a percent of Basic Equipment. If in doubt, detailed estimates should be made.							
MISCELLANEOUS Includes site preparation, painting & other items not accounted for above	Top of range: large complicated processes Bottom of range: smaller, simple processes	RANGE FOR ALL VALUES OF BASIC EQUIPMENT 6 TO 1%						

BUILDING EVALUATION

when most of process units are located inside buildings

QUALITY OF CONST.	HIGH Brick & Steel	MEDIUM		LOW Economical	EVALUATION
	+4	+2		0	
TYPE OF EQUIPMENT	VERY HIGH UNIT COST EQUIPMENT	MOSTLY ALLOY STEEL	MIXED MATERIALS	MOSTLY CARBON STEEL	
	-3	-2	-1	0	
OPERATING PRESSURES	VERY HIGH	INTERMEDIATE		ATMOS.	
	- 2	-1		0	
			BUILDING CLASS = ALGEBRAIC SUM =		

NOTE: When building specifications and dimensions are known, a high-speed building cost estimate is recommended especially if buildings are a significant item of cost. If a seperate estimate is not possible, evaluate the buildings as above before selecting the features

BUILDINGS: ARCHITECTUAL & STRUCTURAL (excludes building services)

	BLDG. CLASS	AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $98M	OVER $98M
MOST OF PROCESS UNITS INSIDE BUILDINGS	+2	92/68	82/61	74/56	67/49	59/44	52/39	46/33
	+1 TO -1	72/49	62/43	56/38	51/33	45/29	41/26	36/21
	-2	50/37	44/33	40/29	35/25	30/21	27/18	23/15
OPEN-AIR PLANTS WITH MINOR BUILDINGS		37/16	32/13	28/11	24/8	20/6	17/4	14/2

BUILDING SERVICES

NOTE: The following factors are for Battery Limit (process) buildings only and are expressed in percent of Building-Architectual & Structural cost. They are not related to the Basic Equipment cost.

	HIGH	AVG.	LOW
Compressed air for general service only	4	2	5
Electric lighting	18	9	5
Sprinklers	10	6	3
Plumbing	20	12	3
Heating	25	16	8
Ventilation without air conditioning	18	8	0
Ventilation with air conditioning	45	35	25
TOTAL OVER-ALL AVERAGE*	85	55	20

The above factors apply to those items normally classified as building services. They do not include:
1. Services located outside the building such as sub-stations, outside sewers, outside water lines etc., all of which are considered to be outside the Battery Limit, as well as outside the building
2. Process services

* The totals provide the ranges for the type of building involved and are useful when the individual service requirements are not known. Note that the over-all averages are not the sum of individual columns

STORAGE AND HANDLING IN PERCENT OF BATTERY-LIMIT COST

	Grass Roots Plant	B/L Addition on Existing Site
	% of B/L Cost	
LOW: Raw material by pipeline. Little warehouse space	2	0 ——→
AVG: Average raw material storage & finish-product warehousing	15 - 25	2 - 6
HIGH: Tank farm for raw- material. Substantial warehousing for finished product	70	20

UTILITIES IN PERCENT OF BATTERY-LIMIT COST

		Range for Grass Roots
Utilities buildings		3 - 10
Architectual & Structural	2 - 7	
Mechanical Services	0.5 - 4	
Compressed Air System		0.1 - 4
Electrical Systems		1.5 - 6
Substation	0.5 - 3.5	
Distribution	0.5 - 3	
Outside Lighting	0.15 - 1.5	
Gas System		0 - 0.6
Sewers & Drainage System		1.3 - 3.5
Steam System		1.5 - 11
Generation	1 - 9	
Distribution	0.5 - 3	
Water System		1 - 10
Pumphouse	1 - 8	
Cooling Towers & recirculation	0.5 - 5	
Distribution	0.15 - 3	
Fire Protection	0.2 - 1	
Water Treatment	0.2 - 1.5	
Miscellaneous		0.5 - 3

	Grass Roots			B/L Additions		
	Low	Avg	High	Low	Avg	High
Over-all averages for all utilities	10	23 - 30	50	3	6 - 14	30

SERVICES IN PERCENT OF (B/L + S&H + U)

	Range for Grass Roots
Main Office	1 - 5
Laboratories	0 - 2.5
Shops & Stores	1 - 8
Lunch Rooms	0 - 2.2
Change Houses	0 - 2.2
Personnel & Gatehouses	0 - 1
Roads, Railroads & Fences	1.3 - 5.5
Service Equipment	0.5 - 4.5
Miscellaneous	0.5 - 2

	Grass Roots			B/L Additions		
	Low	Avg.	High	Low	Avg.	High
Over-all averages for total services	5	10 - 16	20	0	2 - 6	15

CALCULATION SHEET FOR FACTOR ESTIMATING

Division & Location	Proj. or Study No. Requested by	TITLE CAPACITY			DATE
NO. of M.P.I.'s	COST INDEXES 1999 / CURRENT	FACTOR OR ACCURACY	LOW	PROBABLE	HIGH
AVERAGE UNIT COST OF M.P.I.'S IN 1999 DOLLARS					
M.P.I (main plant items)		Estimated			
M.U.E. (Miscellaneous unlisted equipment)					
BASIC EQUIPMENT (M.P.I.+M.U.E.) (EXCLUDING SALES TAXES)		100			
	REMARKS				
Field erection of Basic Equipment					
Equipment Foundations & Structural supports					
PIPING					
INSULATION					
Equipment					
Piping					
Electrical					
Instrumentation					
Miscellaneous					
Buildings: Arch'l & Struc'l					
BUILDING SERVICES:					
Low % of Arch'l & Struct.					
Compressed air					
Electrical lighting					
Insulation					
Plumbing					
Heating					
Vent & Air Conditioning					
TOTAL BLD. SVC.					
SUB TOTAL-FACTORED ITEMS					
ADJUSTMENTS LOWS= HIGHS=					
TOTAL FACTORED ITEMS ADJUSTED					
DIRECT COST OF B/L (excluding taxes)					

SUMMARY SHEET FOR FACTOR ESTIMATING

Division & Location	Proj. or Study No. Requested By	TITLE CAPACITY	DATE

	FACTOR OR ACCURACY	LOW	PROBABLE	HIGH
DIRECT COST OF B/L				
STORAGE AND HANDLING				
UTILITIES				
SERVICES (in per cent of B/L + S&H + U)				
TOTAL B/L + AUXILIARIES				
TAXES				
TOTAL DIRECT COST				
INDIRECT COSTS:				
CONSTRUCTION FIELD, O.H. & PROFIT				
ROYALTIES, LICENCES AND PATENTS				
ENGINEERING				
TOTAL INDIRECT COSTS				
TOTAL DIRECT AND INDIRECT				
CONTINGENCIES				
TOTAL APPROPRIATION				

THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Code of Federal Regulations Title 21, Part 113

CONTENTS

21 CFR PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

AUTHORITY: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

SOURCE: 44 FR 16215, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Aseptic processing and packaging* means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) *Bleeders* means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) *Come-up-time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) *Commercial processor* includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(e) *Commercial sterility*:

(1) "Commercial sterility" of thermally processed food means the condition achieved—

(i) By the application of heat which renders the food free of—

(*a*) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(*b*) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(2) "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) *Critical factor* means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) *Flame sterilizer* means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(h) *Headspace, gross* is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(i) *Headspace, net* of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed container* means a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing.

(k) *Incubation* means the holding of a sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.

(l) *Initial temperature* means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(m) *Lot* means that amount of a product produced during a period of time indicated by a specific code.

(n) *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(o) *Minimum thermal process* means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.
(p) *Operating process* means the process selected by the processor that equals or exceeds the minimum requirements set forth in the scheduled process.
(q) *Retort* means any closed vessel or other equipment used for the thermal processing of foods.
(r) *Scheduled process* means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.
(s) *Shall* is used to state mandatory requirements.
(t) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.
(u) *Vacuum-packed products* means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.
(v) *Vents* means openings through the retort shell, controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.
(w) *Water activity* (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 113.5 Current good manufacturing practice.

The criteria in §§ 113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 113.10 Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

Subpart B—[Reserved]

Subpart C—Equipment

§ 113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts—*
(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks that specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

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(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder which emits steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. The steam controller may be air-operated and actuated by a temperature sensor positioned near the mercury-in-glass thermometer in the retort; a steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of this pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1 1/2 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. For horizontal still retorts, bleeders shall be located within approximately 1 foot of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.

(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

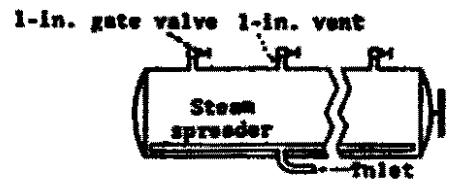
(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold

connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or ot adequate type valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is lar than the total cross-sectional area of all connecting vents. The discharge shall not be directly connectec a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifc from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a va. and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall n begin until the retort has been properly vented and the processing temperature has been reached. Some typie installations and operating procedures reflecting the requirements of this section for venting still retorts a given in paragraph (a)(12)(i)(*a*) through (*d*) and (ii)(*a*) and (*b*) of this section.

(i) *Venting horizontal retorts.*

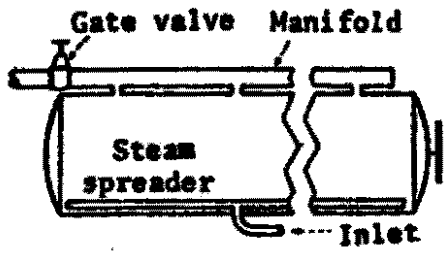
(*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2 1/2 feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225°F, or at least 7 minutes and to at least 220°F.

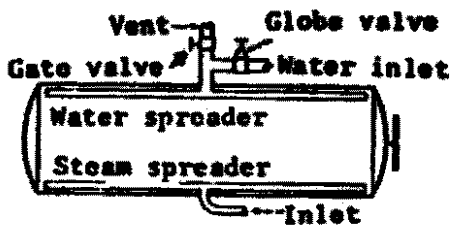
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; and vents not over 2 1/2 feet from ends of retort: Size of manifold for retorts less than 15 feet in length, 2 1/2 inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225°F, or for at least 8 minutes and to at least 220°F.

(*c*) Venting through water spreaders.

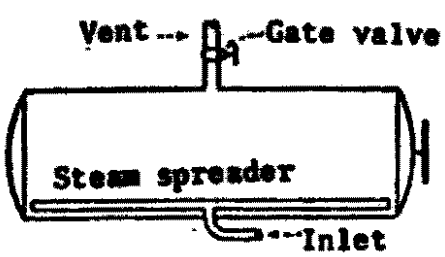


Size of vent and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2 1/2 inches.

Size of water spreader. For retorts less than 15 feet in length, 1 1/2 inches; for retorts 15 feet and over in length, 2 inches. The number of holes should be such that their total cross-sectional area is approximately equal to the cross-sectional area of the vent pipe inlet.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225°F, or for at least 7 minutes and to at least 220°F.

(*d*) Venting through a single 2 1/2-inch top vent (for retorts not exceeding 15 feet in length).

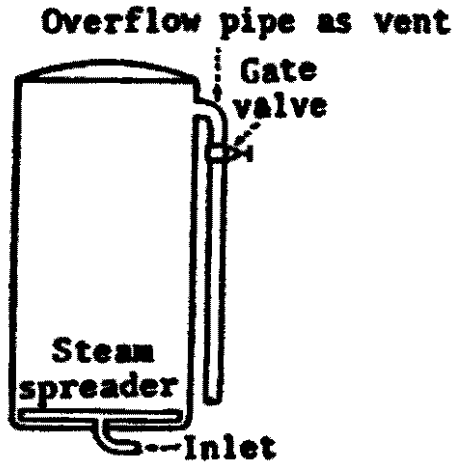


Specifications. A 2 1/2-inch vent equipped with a 2 1/2-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220°F.

(ii) *Venting vertical retorts.*

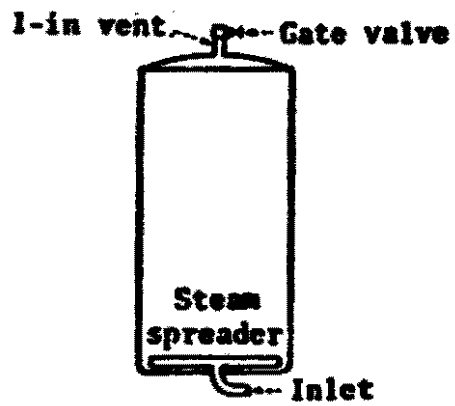
(*a*) Venting through a 1 1/2-inch overflow.



Specifications. A 1 1/2-inch overflow pipe equipped with a 1 1/2-inch gate or plug cock valve and with not more than 6 feet of 1 1/2-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218°F, or for at least 5 minutes and to at least 215°F.

(*b*) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230°F, or for at least 7 minutes and to at least 220°F.

(iii) Other installations and operating procedures that deviate from the above specifications may be used if there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts*—

(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used,

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and person performing the test should be maintained. Each thermometer should have a tag, seal, or oth means of identity that includes the date when it was last tested for accuracy. A thermometer that has a divide mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further us of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicatin thermometers shall be located in such a position that they are beneath the surface of the water throughou the process. On horizontal retorts, this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording-thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts, the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the control bulb. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.*

(i) Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1 1/2-inch clearance between the side wall of the crate and the retort wall.

(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process. Dividers, racks, trays, or other means of positioning of flexible containers shall be designed and employed to ensure even circulation of heating medium around all containers in the retort.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. Screens should be installed over all drain openings.

(9) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, e.g., by using a gage, water glass, or petcock(s). Water shall cover the top layer of containers during the entire come-up-time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(10) (i) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the come-up-time and during processing and cooling periods; the adequacy of the air or water circulation for uniform heat distribution within the retort shall be established in accordance

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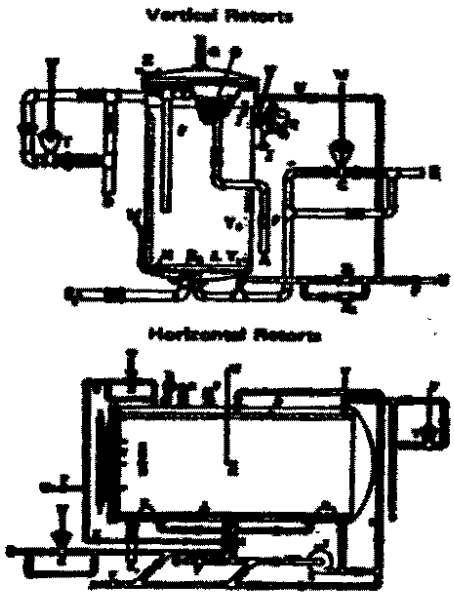
with procedures recognized by a competent processing authority and records shall be kept on file; if air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

(ii) *Water circulation.* When a water circulating system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross-section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warm the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.

(11) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

(12) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(13) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams below in this paragraph. Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, that demonstrates that the heat distribution is adequate.



Legend for Vertical and Horizontal Still Retorts

A — Water line.
B — Steam line.
C — Temperature control.
D — Overflow line.
E_1 — Drain line.
E_2 — Screens.
F — Check valves.
G — Line from hot water storage.
H — Suction line and manifold.
I — Circulating pump.
J — Petcocks.
K — Recirculating line.
L — Steam distributor.
M — Temperature controller bulb.
N — Thermometer.
O — Water spreader.
P — Safety valve.
Q — Vent valve for steam processing.
R — Pressure gage.
S — Inlet air control.
T — Pressure control.
U — Air line.
V — To pressure control instrument.
W — To temperature control instrument.
X — Wing nuts.
Y_1 — Crate support.
Y_2 — Crate guides.
Z — Constant flow orifice valve.
Z_1 — Constant flow orifice valve used during come-up.
Z_2 — Constant flow orifice valve used during cook.

(14) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts—*

(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F

per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standa thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensu their accuracy. Records of thermometer accuracy checks which specify date, standard used, method use and person performing the test should be maintained. Each thermometer should have a tag, seal, or oth means of identity that includes the date on which it was last tested for accuracy. A thermometer that has divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before furth use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs i. indicating thermometers shall be installed either within the retort shell or in external wells attached to th retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam pas the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrumen for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage that should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eight inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed.

or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10°F or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10°F, a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are used, no containers may enter the retort and the process and procedures used shall be noted on the production records.

(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lapseam (vent hole) cans may be measured by net weight determinations. The headspace of double seamed cans may also be measured by net weight determinations for homogeneous liquids, taking into account the specific can end profile and other factors which affect the headspace, if proof of the accuracy of such measurements is maintained and the procedure and resultant headspace is in accordance with the scheduled process. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts—*

(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening, and equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

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(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the come-up-time. Bleeders shall be located within approximately 1 foot of the outermost location of containers, at each end along the top of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for containing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the schedules process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products for which deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts—*

(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard use, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means

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of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment, is a satisfactory means of preventing unauthorized changes.

(6) *Air supply and controls.* Means shall be provided for introducing compressed air at the proper pressure and rate, which shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—

(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometer shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. The thermometer shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Graduation on the temperature-recording devices shall not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature-recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Each temperature-recorder bulb well shall have a 1/16-inch or larger bleeder opening which emits steam continuously during the processing period. Additional temperature-recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specified maintenance of particular temperatures in the hydrostatic water legs. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean dry air.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Recording of temperatures.* Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully mechanically maintained so that it operates satisfactorily.

(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(7) *Bleeders.* Bleeder openings 1/4-inch or larger shall be located at the top of the steam chamber or chambers opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(8) *Retort speed.* The speed of the container-conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems* —

(1) *Product sterilizer* —

(i) *Equipment* —

(*a*) *Temperature-indicating device.* Each product sterilizer shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device, such as a thermocouple-recorder. Mercury-in-glass thermometers shall have divisions that are easily readable to 1°F and whose temperature range does not exceed 17°F per inch of graduated scale. Thermometers and temperature-indicating devices shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary, to ensure their accuracy. Records of accuracy checks which specify date, standard used, method used, and person performing the test should be maintained. Each thermometer and temperature-indicating device

should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to essential agreement with the standard shall be repaired or replaced. Thermometers and temperature-indicating devices shall be installed where they can be accurately and easily read. The temperature-indicating device shall be the reference instrument for indicating the processing temperature.

(*b*) *Temperature-recording device.* There shall be an accurate temperature recording device on each product sterilizer. The device shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Temperature-recording devices shall have graduations that do not exceed 2°F within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the desired product-sterilization temperature. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, a known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

(*c*) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of ensuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2°F within a range of 10°F of the desired product sterilization temperature. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.

(*d*) *Product-to-product regenerators.* When a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.

(*e*) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on the working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(*f*) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(*g*) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 inch per foot.

(*h*) *Flow-diversion systems.* If a processor elects to install a flow-diversion system, it should be installed in the product piping located between the product cooler and the product filler or aseptic surge tank and should be designed to divert flow away from the filler or aseptic surge tank automatically. Controls and/or warning systems should be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits. Flow-diversion systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.

(*i*) *Equipment downstream from the holding tube.* Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system should be equipped with steam seals or other effective barriers at the potential access points. Appropriate means should be provided to permit the operator to monitor the performance of the seals or barriers during operations.

(ii) *Operation* —

(*a*) *Startup.* Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product-sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge tank by means of a flow-diversion system. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with § 113.89. The product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.

(c) *Loss of proper pressures in the regenerator.* When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch greater than the pressure of unsterilized product in the regenerator. In this case, product flow should be diverted away from the filler or aseptic surge tank by means of the flow-diversion system. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process and shall be reprocessed or destroyed. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Loss of sterile air pressure or other protection level in the aseptic surge tank.* When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process value. Product flow to and/or from the aseptic surge tank shall not be resumed until the potentially contaminated product in the tank is removed, and the aseptic surge tank has been returned to a condition of commercial sterility.

(e) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature-indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate as established by the metering pump or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and proper performance of seam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation* —

(i) *Equipment* —

(a) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(ii) *Operation* —

(a) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated and handled in accordance with § 113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization condi-

tions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the test results should be maintained.

(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(1) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.

(2) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to ensure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods shall be as established in the scheduled process. These systems shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

§ 113.60 Containers.

(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the res therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seam station to ensure maintenance of seam integrity. Such examinations and recordings should be made at inter not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective act taken, if any, shall be noted.

(i) Required and optional can seam measurements:

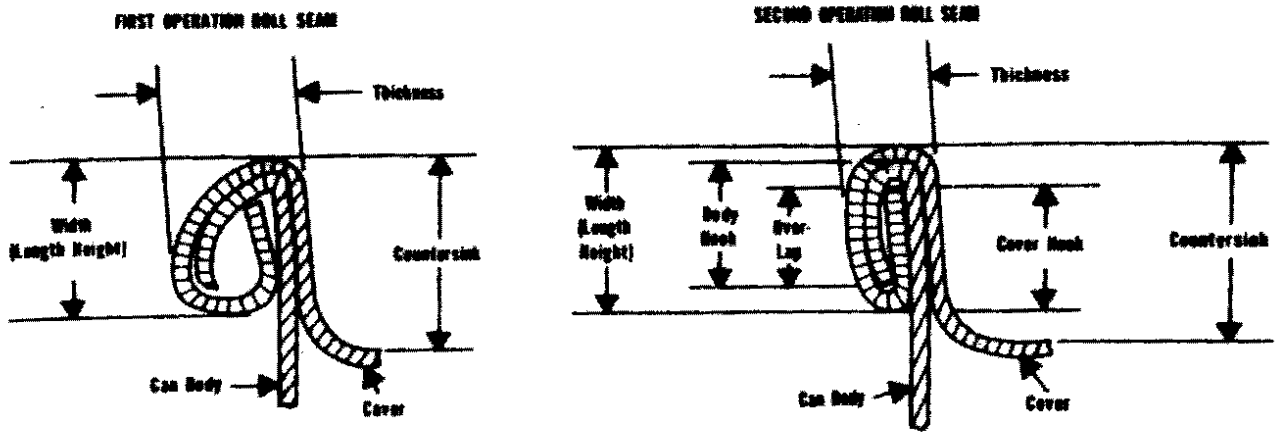
(*a*) Micrometer measurement system:

Required	Optional
Cover hook Body hook Width (length, height) Tightness (observation for wrinkle) Thickness	Overlap (by calculation) Countersink

(*b*) Seam scope or projector:

Required	Optional
Body hook Overlap Tightness (observation for wrinkle) Thickness by micrometer	Width (length, height) Cover hook Countersink

(*c*) Can double seam terminology:



(*1*) "Crossover": The portion of a double seam at the lap.

(*2*) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam.

(*3*) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink.

(*4*) "Droop": Smooth projection of double seam below bottom of normal seam.

(*5*) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped.

(*6*) "Lap": Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

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(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length =

CH + BH + T-W, where

CH = cover hook

BH = body hook

T = cover thickness, and

W = seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* When cans are handled on belt conveyors, the conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated as to preserve the can seam or other container closure integrity.

Subpart E—Production and Process Controls

§ 113.81 Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in § 114.90 of this chapter should be used.

(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity (a_w) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an a_w greater than 0.85 and less than the a_w that would allow the growth of spores of microorganisms

of public health significance shall be sufficient to render the food free of microorganisms capable of reproducin in the food under normal nonrefrigerated conditions of storage and distribution.

§ 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of therma processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for makin such determinations. The type, range, and combination of variations encountered in commercial production shall b adequately provided for in establishing the scheduled process. Critical factors, e.g., minimum headspace, consistency maximum fill-in or drained weight, a_w, etc., that may affect the scheduled process, shall be specified in the schedule process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 113.87 Operations in the thermal processing room.

(a) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A written record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.

(e) Clock times on recording-temperature charts should reasonably correspond to the time of day on the written processing records to provide correlation of these records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority.

§ 113.89 Deviations in processing, venting, or control of critical factors.

Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential

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public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those deviations and the actions taken.

Subpart F—Records and Reports

§ 113.100 Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.

(6) *Food preservation methods wherein critical factors such as water activity are used in conjunction with thermal processing.* Product formulation and scheduled processes used, including the thermal process, its associated critical factors, as well as other critical factors, and results of a_w determinations.

(7) *Other systems.* Critical factors specified in the formulation of the product or in the scheduled process.

(b) Recording thermometer charts shall be identified by date, retort number, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later that 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed.

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(d) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(e) Copies of all records provided for in this part, except those required under § 113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.