

306

REGS 1023a

Regulatory Development and Implementation, and Dockets

Final rulemakings and related development and implementation records

Close when end of
calendar year occurs
or when action is
completed.

+ 1 year

+ 14 years



Close Date

07/07/2003

Retire Date

10/01/2004

Final Disposition Date

01/01/2019

Final Disposition Action:



Destroy

or



Permanently Transfer

United States Environmental Protection Agency

03/31/2016

306

REGS 1023a

Regulatory Development and Implementation, and Dockets
Final rulemakings and related development and implementation records

Close when end of
calendar year occurs
or when action is
completed.

+ 1 year

+ 14 years

Close Date

07/07/2003

Retire Date

10/01/2004

Final Disposition Date

01/01/2019

Final Disposition Action:

☐

Destroy

or

☒

Permanently Transfer

United States Environmental Protection Agency

03/31/2016

306

REGS 1023a

Regulatory Development and Implementation, and Dockets
Final rulemakings and related development and
implementation records

Close when end of
calendar year occurs
or when action is
completed.

+ 1 year

+ 14 years

Close Date

07/07/2003

Retire Date

10/01/2004

Final Disposition Date

01/01/2019

Final Disposition Action:



Destroy

or



Permanently Transfer

United States Environmental Protection Agency

03/31/2016

306

REGS 1023a

Regulatory Development and Implementation, and Dockets
Final rulemakings and related development and
implementation records

+ 14 years

+ 1 year

Close when end of
calendar year occurs
or when action is
completed.

Close Date

07/07/2003

Retire Date

10/01/2004

Final Disposition Date

01/01/2019

Final Disposition Action:

☐ Destroy or

☒ Permanently Transfer

03/31/2016

United States Environmental Protection Agency

REGS 123a. State Program Authorization/
Approval Files Kansas Promulgation: CLEAN WATER ACT:
ADMINISTRATIVE RECORD FOR FINAL PROMULGATION OF KANSAS
WATER QUALITY STANDARDS: VOLUME 4.

306

REGS 1023a

Regulatory Development and Implementation, and Dockets
Final rulemakings and related development and
implementation records

Close when end of
calendar year occurs
or when action is
completed.

	+ 1 year	+ 14 years
Close Date	Retire Date	Final Disposition Date
07/07/2003	10/01/2004	01/01/2019

Final Disposition Action: ☐ Destroy or ☒ Permanently Transfer
United States Environmental Protection Agency 03/31/2016

8115-00-117-8240
BOX, SHIPPING, FIREBOARD, SPECIAL PURPOSE
(RECORDS RETURNING)
-ATDC, 1" ACC MAGNETIC, STYLE C, 275, B

PLEASE REMOVE
QUESTIONS

DO NOT WRITE ON THIS END

FRONT

DO NOT WRITE

DO NOT WRITE ON THIS END

INSTRUCTIONS (1 OF 2)

1. DO NOT OBLISCURE BOX NUMBER OR ACCESSION NUMBER WITH TAPE
2. USE BLACK FELT WIDE-TIP MARKER
3. MAKE NUMBERS 3.81cm (1-1/2 INCHES) HIGH
4. PACK NUMBERS WITH RECORDS ONLY
5. LETTER-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
6. LEGAL-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
7. LABELS ON MAGNETIC TAPE REELS MUST FACE THE FRONT OF THE MAGNETIC TAPE BOX

INSTRUCTIONS (1 OF 2)

1. DO NOT OBLISCURE BOX NUMBER OR ACCESSION NUMBER WITH TAPE
2. USE BLACK FELT WIDE-TIP MARKER
3. MAKE NUMBERS 3.81cm (1-1/2 INCHES) HIGH
4. PACK NUMBERS WITH RECORDS ONLY
5. LETTER-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
6. LEGAL-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
7. LABELS ON MAGNETIC TAPE REELS MUST FACE THE FRONT OF THE MAGNETIC TAPE BOX

INSTRUCTIONS (2 OF 2)

1. PRINT THE ACCESSION NUMBER ON THE UPPER LEFT FRONT OF THE BOX
2. PRINT THE BOX NUMBER ON THE UPPER RIGHT FRONT OF THE BOX
3. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
4. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
5. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
6. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
7. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
8. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
9. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
10. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX

ON THIS END

ON THIS END

ON THIS END

INSTRUCTIONS (1 OF 2)

1. DO NOT OBLISCURE BOX NUMBER OR ACCESSION NUMBER WITH TAPE
2. USE BLACK FELT WIDE-TIP MARKER
3. MAKE NUMBERS 3.81cm (1-1/2 INCHES) HIGH
4. PACK NUMBERS WITH RECORDS ONLY
5. LETTER-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
6. LEGAL-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
7. LABELS ON MAGNETIC TAPE REELS MUST FACE THE FRONT OF THE MAGNETIC TAPE BOX

INSTRUCTIONS (1 OF 2)

1. DO NOT OBLISCURE BOX NUMBER OR ACCESSION NUMBER WITH TAPE
2. USE BLACK FELT WIDE-TIP MARKER
3. MAKE NUMBERS 3.81cm (1-1/2 INCHES) HIGH
4. PACK NUMBERS WITH RECORDS ONLY
5. LETTER-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
6. LEGAL-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
7. LABELS ON MAGNETIC TAPE REELS MUST FACE THE FRONT OF THE MAGNETIC TAPE BOX

INSTRUCTIONS (1 OF 2)

1. DO NOT OBLISCURE BOX NUMBER OR ACCESSION NUMBER WITH TAPE
2. USE BLACK FELT WIDE-TIP MARKER
3. MAKE NUMBERS 3.81cm (1-1/2 INCHES) HIGH
4. PACK NUMBERS WITH RECORDS ONLY
5. LETTER-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
6. LEGAL-SIZE FILES MUST BE PLACED IN ORDER BY NAME, NUMBER, OR DATE
7. LABELS ON MAGNETIC TAPE REELS MUST FACE THE FRONT OF THE MAGNETIC TAPE BOX

INSTRUCTIONS (2 OF 2)



1. PRINT THE ACCESSION NUMBER ON THE UPPER LEFT FRONT OF THE BOX
2. PRINT THE BOX NUMBER ON THE UPPER RIGHT FRONT OF THE BOX
3. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
4. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
5. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
6. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
7. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
8. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX
9. PRINT THE DATE OF THE BOX ON THE LOWER LEFT FRONT OF THE BOX
10. PRINT THE DATE OF THE BOX ON THE LOWER RIGHT FRONT OF THE BOX

FRONT

ACCESSION NUMBER

DATE

Environmental Protection Agency
 1301 Constitution Avenue NW, Washington DC, 20004
 Khesha Reed
 Documents
 202-407-0507
 202-407-0507
reed.khesha@epa.gov
 June 25
 18 Wet/Moldy Boxes
 Document Recovery

BMS CAT Freeze Drying and/or Document Cleaning Quotation Based on GSA Schedule for Emergency Services				
	Quantity of Boxes	Size of Boxes in Cubic Feet	Cubic Feet or Unit Price	Price for Each Category of Service
	18	1 2	21.6	
© BMS Cat, Inc. 2009				
				
Contract #GS-07F-0087T				
BMS CAT Freeze Dry Process			\$28.95	\$ 625.32
Project Administration (This is for inventorying, auditing, special tasks, consulting, etc. This work is not performed on the project site but at the regional service center or at Fort Worth.)				\$ 90.05
Cleaning & Inspection of files per 1.2 cu/ft. box			\$ 41.59	\$ 900.50
	Cubic feet of boxes with charred documents. ↓		Price per cubic foot. ↓	
Sanitizing (filter/drain)			\$ 10.86	\$ 234.58

Onsite Labor, Travel & equipment. <i>(This applies for a field BMS pack out.)</i>				\$	700.00
BMS CAT boxes.				\$	75.60
Freight from client to BMS by client.				\$	505.00
Freight from BMS back to client. Paid for by clients UPS or Fed Ex account number.				\$	505.00
Total Estimate				\$	3,636.05

Documents must be paid for in advance of shipping back to client. Retainers and progress payments are required while work is being performed.

VALUE: Customer declares, for the purposes of this Agreement, that (a) with respect to hard-copy (paper) records, microfilm and microfiche stored pursuant to this Agreement, the value of such stored items is \$1.00 per carton and (b) with respect to round reel tape, audio tape, video tape, film, data tape, cartridges or cassettes or other non-paper media stored pursuant to this Agreement, the value of such stored items is equal to the cost of replacing the physical media.

LIMITATION OF LIABILITY: BMS CAT's liability, if any, for loss or destruction of, or damage to, materials while in BMS CAT's custody is limited to the value of each carton as described above.

Document Recovery Work Authorization↓

Customer agrees to pay BMS CAT for all labor, materials, equipment and expenses utilized to mobilize, commence and perform the work described above in accordance with this Document Pricing Matrix Estimate. Customer acknowledges that they have reviewed the charges and terms of payment on the Estimate and agree that they are reasonable and that they will not attempt to renegotiate them, or any part of them, after BMS CAT commences performance of the Work.

Signature	
Name	
Title	
Date	

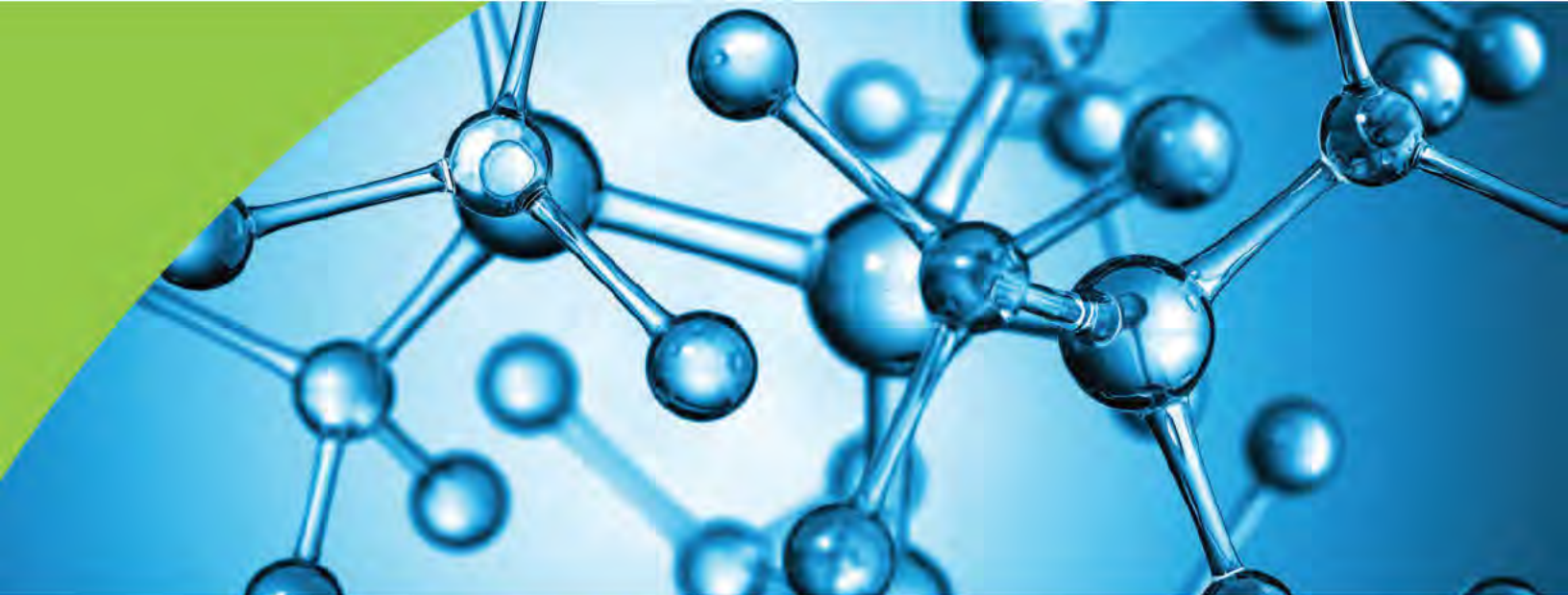


Material Consideration Radiation Processing



The Global Leader in Comprehensive
Sterilization Solutions

sterigenics.com



Radiation's Effects

Radiation interacts with polymers in two ways: chain scission, which results in reduced tensile strength and elongation; and crosslinking, which increases tensile strength but reduces elongation. Both reactions occur simultaneously, but one is usually dominant, depending upon the specific polymer and additives involved.

Chain scission classically affects stressed polymers (containing residual molding stress) to a greater extent than non-stressed polymers. The combined impact of solvent-induced stress, residual molding stress and applied load acts to intensify radiation damage.

Generally, polymers containing aromatic ring structures (e.g. polystyrene) are resistant to radiation effects. Aliphatic polymers exhibit degrees of resistance depending upon their levels of unsaturation and substitution.

Some effects of radiation—such as reduced elongation due to chain scission, may detract from the device's performance. Others can be beneficial. For example, crosslinking of polyethylene and silicones increases tensile strength.

Manufacturers should be cognizant of the possible impact of radiation on mechanical properties such as tensile strength, elastic modulus, impact strength and elongation. Outcomes may influence performance and should be evaluated in advance by functional testing.

Stabilizers and Additives

Additives and stabilizers are commonly included in small amounts (less than 1%) in commercial polymer products to aid in processing, stabilize the material and impart particular properties to the product.

Tint-based, multi-function stabilizers, for example, are added to PVCs to counteract the color change that is typical when this material is irradiated— an important consideration in situations where color plays a strong role in customer reaction to the product. Other additives known as "antirads" function as antioxidants and help prevent radiation damage.

These additives perform either as reactants, which readily combine with radiation-generated free radicals within the polymer, or as primary energy absorbers, preventing the interaction of the radiation energy with the polymer itself.

Material Evaluation

When weighing the radiation stability of a polymer and the ultimate success of a component or medical device, the following factors should be taken into consideration:

- Stabilizers and antioxidants added to a polymer can reduce the effects of irradiation on the product's mechanical properties and/or physical appearance
- Thin part sections, thin films and fibers present in a component or product can allow for excessive oxygen exposure during the irradiation process, thus causing degradation of the polymer material
- Residual mold stress present after molding and assembly of a component or product can promote molecular scissioning during irradiation
- Highly oriented moldings, which are strong in the axis of orientation but are already very weak in the cross-flow axis, will become weaker after irradiation
- High molecular weight polymers having low melt flow will survive radiation better by providing longer molecules and stronger parts before and after irradiation.

Material Compatibility and Validation

Each polymer reacts differently to ionizing radiation. Thus, it is important to verify that the maximum administered dose will not have a detrimental effect on the product's function or the patient's safety over the product's intended shelf life.

Experimental samples of the product should be irradiated to at least the highest dose to be encountered during routine processing. For example, a product which is to receive a sterilizing dosage of 25 to 40 kiloGray (kGy) should be tested by dosing samples to at least 40 kGy. A conservative approach is to irradiate samples at doses up to twice the anticipated maximum dose.

Since various product applications call for certain performance properties or functional characteristics, it is important to test each component or product in an appropriate manner, using both new and aged material.

Table 1 reviews typical tests of physical properties. Other tests, which more closely approximate the actual mechanical application, may also be employed by the engineering or research staff.

Results of the evaluation should be retained in the product's device history file, serving as physical confirmation that all product claims and specifics have been met. If product testing indicates a potentially adverse effect from high levels of radiation, a maximum permissible dose should be established by the manufacturer and emphasized in the specific processing instructions to the contract sterilizer.

Figure A graphically displays the dose ranges at which a number of common thermoplastics and thermosets show significant change in properties (i.e., a 25% loss in elongation). Loss of elongation is a commonly used measure of the effect of irradiation because it equates to a brittleness failure.

This figure also provides a visual means of making an initial estimate of a polymer's ability to withstand a particular radiation sterilization process.

TABLE 1
PHYSICAL AND FUNCTIONAL TEST METHODS FOR PLASTICS MATERIAL EVALUATION

Test Method	Test References
Test for Embrittlement	
1. Tensile properties	
a) Tensile strength	ISO 527 series
b) Ultimate elongation	ISO 527 series
c) Modulus of elasticity	ISO 527 series
d) Work	ISO 527 series
2. Flexural properties	
a) Flange bending test	Stability of Irradiated Polypropylene 1. Mechanical Properties, Williams, Dunn, Sugg, Stannet, Advances in Chemistry Series, No. 169, Stabilization and Degradation of Polymers, Eds. Allara, Hawkins, pp. 142-150, 1978.
b) Flexbar test	ISO 178
3. Impact resistance	ASTM D-1822
4. Hardness	
a) Shore	ISO 868
b) Rockwell	ASTM D-785
5. Compressive strength	ISO 604
6. Burst strength	ASTM F-2054
7. Tear strength	ASTM D-1004 and ISO 6383-1
Test for Discoloration	
1. Yellowness index	ASTM E-313
2. Optical spectrometry	ASTM D-1746

Source: International Atomic Energy Agency. Guidelines for industrial radiation sterilization of disposable medical products. Co-60 gamma irradiation. TEC DOC-539. Vienna IAEA, 1990.

FIGURE A
RELATIVE RADIATION STABILITY OF MEDICAL POLYMER "FAMILIES"



NOTE—HP = high performance; PVC = polyvinylchloride; ABS = acrylonitrile butadiene styrene; PMMA = polymethylmethacrylate; PP = polypropylene; FEP = fluorinated ethylene propylene; PTFE = polytetrafluoroethylene.

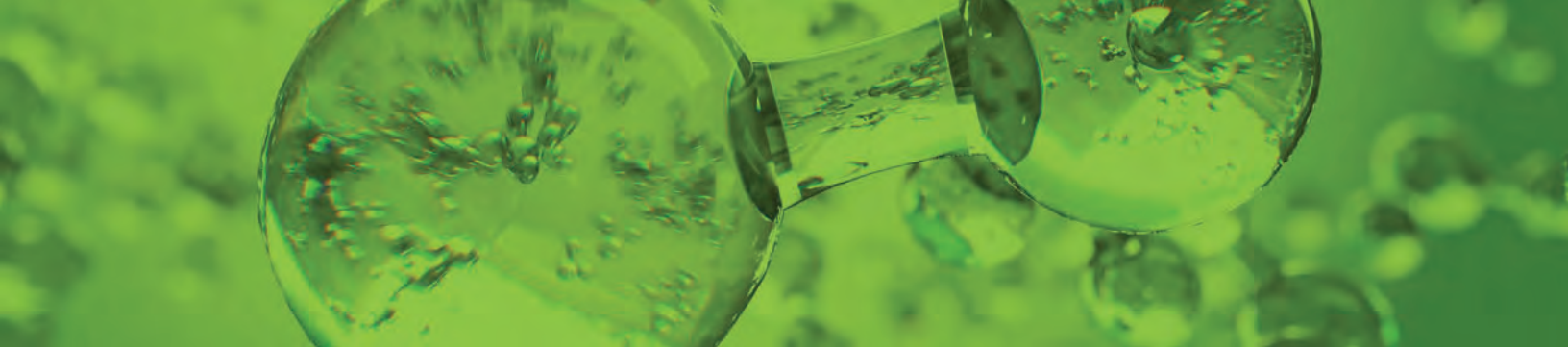


TABLE 2
GENERAL GUIDE TO RADIATION STABILITY OF MATERIALS

Table 2 shows typical radiation resistances of medical polymers in stress-free parts measured at the point where 25% of the polymer’s elongation is lost because of radiation. This circumstance might well be the “best case.” If the part being considered has a significant degree of residual stress as a result of manufacture, the dose at which the 25% loss of elongation occurs can be considerably lower.

(·) = poor (··) = fair (···) = good (····) = excellent (NL) = not likely (L) = likely

Material	Single use (<50 kGy)	Comments	Resterilization (<100 kGy)	Comments
Thermoplastics				
Acrylonitrile butadiene styrene (ABS)	···	High-impact grades are not as radiation resistant as standard impact grades because of the higher butadiene content.	L	
Fluoropolymers				
Polytetrafluoroethylene (PTFE)	·	When irradiated, PTFE and PFA are significantly damaged. The other fluoropolymers show significantly greater stability. Some (for example, PVDF) are excellent.	NL	
Perfluoro alkoxy (PFA)	·		NL	
Perchlorotrifluoroethylene (PCTFE)	··· to ····		L	
Polyvinyl fluoride (PVF)	···		L	
Polyvinylidene fluoride (PVDF)	··· to ····		L	
Ethylenetetrafluoro ethylene (ETFE)	··· to ····		L	
Fluorinated ethylene propylene (FEP)	··		NL	
Polyacetals (e.g., polyoxymethylene)	·	Irradiation causes significant chain scission (i.e., embrittlement). Color changes have been noted (yellow to green).	NL	
Polyacrylates (e.g., polymethylmethacrylate)	·· to ···		NL	
Polyamides (e.g., nylon)	·· to ···	Nylon 10, 11, 12, and 6-6 are more stable than 6. Nylon film and fiber are less resistant.	L	Very dependent on design and use requirements.
Polycarbonate (PC)	··· to ····	Yellows—mechanical properties are not greatly affected; colorcorrected radiation formulations are available.	L	
Polyesters, saturated	·· to ···	Polybutylene terephthalate is not as radiation stable as polyethylene terephthalate resins.	L	
Polyethylene (PE), various densities	··· to ····	High-density polyethylene is not as stable as mediumdensity polyethylene and low-density polyethylene, linear lowdensity polyethylene.	L	
Polyimides (e.g., polyetherimide)	····		L	
Polyketones (e.g., polyetheretherketone)	····		L	

TABLE 2 (Continued)
GENERAL GUIDE TO RADIATION STABILITY OF MATERIALS

(-) = poor (-) = fair (••) = good (•••) = excellent

(NL) = not likely (L) = likely

Material	Single use (<50 kGy)	Comments	Resterilization (<100 kGy)	Comments
Polypropylene (PP)				
Natural	• to ••	Physical properties are greatly reduced when irradiated (for example, chain scissioning). Radiation-stabilized grades, using high molecular weight, copolymerized and alloyed with polyethylene, with additional stabilizers should be used in most radiation applications. Use of electron beam at high dose rate may reduce oxidative degradation.	NL	
Stabilized	•• to •••		NL	
Polystyrene (PS)	••••	Will begin to yellow at >50 kGy.	L	
Polysulfones	••••	Natural material is yellowish.	L	
Polyurethane (PU)	•• to ••••	Aromatic discolors; polyesters are more stable than esters. Retains physical properties.	L	
Polyvinylacetates (PVA)	•••		NL	
Polyvinylchloride (PVC)	•••	Cross-linking dominates and significant yellow color development occurs at doses > 30 kGy. Addition of antioxidants and heat stabilizers to formulations will retard color development. High-molecular-weight organotin stabilizers improve radiation stability; color-corrected radiation formulations are available.	NL	Significant discoloration likely.
PVC, plasticized	•••	Cross-linking (stiffening) dominates.	L	Discoloration likely.
Styrene acrylonitrile (SAN)	••• to ••••		L	
Thermosets				
Epoxy	••••		L	
Phenolics	••••	Includes the addition of mineral fillers.	L	
Polyester, unsaturated	••••	Includes the addition of mineral or glass fibers.	L	
Polyimides	••••		L	
Polyurethanes				
Aliphatic	••••		L	
Aromatic	••• to ••••	Darkening can occur. Possible breakdown products could be derived.	L	
Adhesives				
Acrylic	•• to •••		L	Embrittlement possible.
Epoxy	••••		L	
Fluoroepoxy	••••		L	
Silicone	•• to •••		L	
Elastomers				
Butyl	•	Friable, sheds particulate, chain scission.	NL	
Ethylene propylene diene monomer (EPDM)	••• to ••••		L	
Natural rubber	••• to ••••		L	

TABLE 2 (Continued)
GENERAL GUIDE TO RADIATION STABILITY OF MATERIALS

(-) = poor (••) = fair (•••) = good (••••) = excellent

(NL) = not likely (L) = likely

Material	Single use (<50 kGy)	Comments	Resterilization (<100 kGy)	Comments
Nitrile	••• to ••••	Discolors.	L	
Polyacrylic	•• to •••		NL	
Polychloroprene	•••	Discolors; the addition of aromatic plasticizers renders the material more stable to irradiation.	L	
Silicone	•• to •••	Cross-linking dominates. Platinum-cured silicones are superior to peroxidecured silicones because their preirradiation cross-link density is greater. Full cure during manufacture can reduce postirradiation cross-link effects. Phenyl-methyl silicones are more stable than are methyl silicones.	L	Stiffening due to cross-linking likely.
Styrenic block copolymers (e.g., styrene-butadienestyrene, styrene-ethylenebutylene-styrene)	•• to •••	Butadiene scissions.	L	
Urethane	••• to ••••		L	
Metals				
Aluminum	••••		L	
Brass	••••		L	
Copper	••••		L	
Gold	••••		L	
Magnesium	••••		L	
Nickel	••••		L	
Silver	••••		L	
Stainless steel	••••		L	
Titanium	••••		L	
Ceramics/glasses				
Aluminum oxides	••••		L	
Silica	••••		L	
Zirconium oxides	••••		L	
Other materials				
Bioabsorbables				
Polyglycolides	• to ••••		NL	
Poly lactides	• to ••••		NL	
Cellulosics				
Cellulose ester	••	Esters degrade less than other cellulosics.	NL	
Cellulose acetate propionate	•• to ••••		L	
Cellulose acetate butyrate	•• to ••••		L	
Cellulose, paper, cardboard	•• to ••••		L	
Liquid crystal polymer (LCP)	• to ••••	Commercial LCPs; natural LCPs are not stable.	L	



References

Primary sources: International Atomic Energy Agency; NASA/Jet Propulsion Laboratory; and polymer manufacturers' literature.

AAMI TIR 17, Compatibility of materials subject to sterilization (for Table 2 and Figure A).

- 1 AAMI TIR29, Guide for process characterization and control in radiation sterilization of medical devices.
- 2 ANSI/AAMI/ISO 11137-1, Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.
- 3 Genova, Hollis, Crowell and Schady, "A Procedure for Validating the Sterility of an Individual Gamma Radiation Sterilized Production Batch," *Journal of Parenteral Science and Technology*, Volume 41, No.1, pp. 33-36, Jan 1987.
- 4 Gaughran and Morrissey, "Sterilization of Medical Products," Volume 2, ISBN-0-919868-14-2, pp. 35-39, 1980.

Comprehensive Sterilization Solutions

We are over 1600 engineers, scientists, safety specialists and solution providers focused on eliminating threats to the health of humanity. We have global breadth and more than 90 years of deep expertise across Gamma, EO, E-Beam and X-ray sterilization. Our operations span 47 facilities in 13 countries to ensure we are the "point of safe" for our customers.

Safeguarding Global Health™ – with every product we sterilize.



Headquarter Office:
Oak Brook, IL, USA

For more information:
+1 800.472.4508 | [sterigenics.com](https://www.sterigenics.com)



Gamma



The Global Leader in Comprehensive
Sterilization Solutions

sterigenics.com

Gamma

A form of electromagnetic energy characterized by its deep penetration and low dose rates. Gamma irradiators are powered by Cobalt-60, effectively killing microorganisms throughout the product and its packaging with very little temperature effect and no residues. The amount of radiation received depends on the type of product and its dose requirements. Dosimetric release allows products to be processed, verified and immediately released for shipment. Our exclusive ExCell high-precision irradiator delivers precision dosing to within ± 10 percent.

Best Suited for:

- Single-use medical products
- Packaged products
- Food products
- Cosmetics
- Tissue-based devices
- Implantable medical devices (stents, heart valves, orthopedics)
- Pharmaceutical products and packaging
- Combination medical devices that may contain a pharmaceutical or biologic
- Raw materials

Key Benefits:

Gamma sterilization technology is very well understood, safe and easy to validate. It is an effective sterilization method due to its:

Sterility Assurance and Treatment Efficacy:

Consistently meets product and regulatory requirements.

Safety:

Proven track record in worker and product safety.

Flexibility and Versatility:

Effectively sterilizes a wide range of products with different variations in dose requirements, densities and packaging/box sizes.

Reliability:

The reliability and simplicity of the process is unparalleled.

Gamma Facilities



NORTH & SOUTH
AMERICA



EUROPE



ASIA

Comprehensive Sterilization Solutions

We are over 1600 engineers, scientists, safety specialists and solution providers focused on eliminating threats to the health of humanity. We have global breadth and more than 90 years of deep expertise across Gamma, EO, E-Beam and X-ray sterilization. Our operations span 47 facilities in 13 countries to ensure we are the "point of safe" for our customers.

Safeguarding Global Health™ – with every product we sterilize.



Sterigenics.

A Sotera Health company

Headquarter Office:
Oak Brook, IL, USA

For more information:
+1 800.472.4508 | sterigenics.com



Estimate

#EST-0030540

15 Sharpners Pond Rd., Building F
North Andover MA 01845
Phone: 800-422-6379 Fax: 978-655-8511

Date: 6/26/2020

Servicing Office

04-National Documents Dept : Allentown Document Center

Bill To

Khesha Reed
EPA
1301 Constitution Ave NW
Washington DC DC 20004
United States

Ship To

Khesha Reed
EPA
1301 Constitution Ave NW
Washington DC DC 20004
United States

Job Description	Sales Rep	Partner
EPA - Drying and Cleaning 18 Boxes	Segal, Marc	

QTY	Description	Rate	Amount
1	Shipping Charges	\$600.00	\$600.00
21.6	Cleaning Level 1 - Document Per Cubic Ft.	\$60.00	\$1,296.00
10	Document Restoration Specialist - Regular Rate	\$40.00	\$400.00
21.6	Drying per cubic foot for 1-250 cubic feet, per Cube	\$70.00	\$1,512.00
21.6	Stabilization Freezer Storage, Cubic Ft Per Month	\$7.00	\$151.20
21.6	Irradiation - Gamma Ray 81-Up Cube (per cube charge)	\$15.00	\$324.00
18	Boxes Bankers	\$3.00	\$54.00

Subtotal \$4,337.20

Tax (%) \$0.00

Total \$4,337.20



Estimate

#EST-0030540

15 Sharpners Pond Rd., Building F
North Andover MA 01845
Phone: 800-422-6379 Fax: 978-655-8511

Date: 6/26/2020

TERMS AND CONDITIONS

The Parties hereby acknowledge and agree that the terms and conditions found at the following website;
<https://drive.google.com/a/polygongroup.com/file/d/0B4lBi2MAsRSCa3FGVnp4RGZUWGc/view?usp=sharing>
are hereby incorporated herein; and shall not be amended by the Parties without written amendment.

Signature: _____

Date: _____



Marianne Mason <marianne.mason@nara.gov>

Fwd: CREW and EPA

7 messages

Laurence Brewer <laurence.brewer@nara.gov>

Mon, Aug 10, 2020 at 2:59 PM

To: "Cote, Darin" <darin.cote@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, "Kabrel, Jack" <jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Hawkins, Margaret" <margaret.hawkins@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

FYI -- a promising sign.....

----- Forwarded message -----

From: **Laurence Brewer** <laurence.brewer@nara.gov>

Date: Mon, Aug 10, 2020 at 2:57 PM

Subject: Re: CREW and EPA

To: Debra Wall <debra.wall@nara.gov>, Phillips, Meg <meg.phillips@nara.gov>

Cc: Ferriero, David <david.ferriero@nara.gov>, John Valceanu <john.valceanu@nara.gov>, Maria Stanwich <maria.stanwich@nara.gov>, Stern, GaryM <garym.stern@nara.gov>, Trainer, Jay <jay.trainer@nara.gov>, William Bosanko <william.bosanko@nara.gov>

Update -- I just spoke with John Ellis, EPA records officer, who said that this is a misunderstanding and that to the best of his knowledge the records still exist in the DC office where they have been stored. The miscommunication is a result of the EPA facility manager initially reporting that the records were destroyed when in fact they weren't. Because of COVID, access to the building has been limited, but John contacted the facility manager who is going into the building tomorrow, and then John will call me back to confirm.

We also contacted EPA's GC office, and they have also gotten involved and are working with John to help clarify this situation and coordinate a response to CREW's report.

I will let you know the final status once we nail this down.

L.

On Mon, Aug 10, 2020 at 8:22 AM Laurence Brewer <laurence.brewer@nara.gov> wrote:

Thanks, Deb, for forwarding.

This is disturbing. We had been working with EPA in good faith, as was Pamela Najar-Simpson on the remediation end, but obviously I was not aware until I saw this that EPA destroyed the records.

If what CREW has reported (and John Ellis seems to confirm) is accurate, this will now become an unauthorized case, which means our letter to EPA will be posted on our public website.

Before I send the letter opening the case, I'll touch base with NGC and Valchy on the legal/public affairs aspects of this.

I'll keep you informed.

L.

On Fri, Aug 7, 2020 at 8:14 PM Debra Wall <debra.wall@nara.gov> wrote:

Forgot Gary.

On Fri, Aug 7, 2020 at 8:12 PM Debra Wall <debra.wall@nara.gov> wrote:

https://www.citizensforethics.org/epa-destroys-water-quality-records-deceives-archivist/?fbclid=IwAR1nZ8hieCXfSShBNppFhWOkcxLVBzd2WdjTS_7SFW4hi0r1viZEZkpNuU

Laurence Brewer, CRM

Chief Records Officer for the U.S. Government
National Archives and Records Administration

Laurence.Brewer@nara.gov

Office: (301) 837-1539

Ce (b) (6)

Blog: [Records Express](#)



Laurence Brewer <laurence.brewer@nara.gov>

Tue, Aug 11, 2020 at 1:35 PM

To: "Cote, Darin" <darin.cote@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, "Kabrel, Jack" <jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Hawkins, Margaret" <margaret.hawkins@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

John wrote back this morning to let me know that staff on site have confirmed that the boxes are still there.

[Quoted text hidden]

Margaret Hawkins <margaret.hawkins@nara.gov>

Tue, Aug 11, 2020 at 1:43 PM

To: Laurence Brewer <laurence.brewer@nara.gov>

Cc: "Cote, Darin" <darin.cote@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, "Kabrel, Jack"

<jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

So glad to hear tha (b) (5)

[Quoted text hidden]

Laurence Brewer <laurence.brewer@nara.gov>

Tue, Aug 11, 2020 at 1:55 PM

To: Margaret Hawkins <margaret.hawkins@nara.gov>

Cc: "Cote, Darin" <darin.cote@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, "Kabrel, Jack"

<jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

I advised John to get with his PA and SM staff. I will check in with Meg for follow up with SAA.

[Quoted text hidden]

Darin Cote <darin.cote@nara.gov>

Tue, Aug 11, 2020 at 2:08 PM

To: Laurence Brewer <laurence.brewer@nara.gov>

Cc: Margaret Hawkins <margaret.hawkins@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, "Kabrel, Jack" <jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

That's great news.

Darin Côté
Electronic Records Policy Analyst
Policy and Program Support Team (ACPP)
Office of the Chief Records Officer for the U.S. Government
National Archives and Records Administration
w 817.551.2003 (b) (6)



[Quoted text hidden]

Anne Mason <marianne.mason@nara.gov>

Tue, Aug 11, 2020 at 2:10 PM

To: Darin Cote <darin.cote@nara.gov>

Cc: Laurence Brewer <laurence.brewer@nara.gov>, Margaret Hawkins <margaret.hawkins@nara.gov>, "Kabrel, Jack" <jack.kabrel@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

Good news. Let me know if there's anything the FRED team needs to do to follow up on this.

[Quoted text hidden]

—
Anne Mason, CA
Office of the Chief Records Officer, Operations Research and Support Team
Archives Specialist
301-837-3502
marianne.mason@nara.gov

Jack Kabrel <jack.kabrel@nara.gov>

Tue, Aug 11, 2020 at 2:14 PM

To: Laurence Brewer <laurence.brewer@nara.gov>

Cc: "Cote, Darin" <darin.cote@nara.gov>, Marianne Mason <marianne.mason@nara.gov>, Lisa Haralampus <lisa.haralampus@nara.gov>, Carla Simms <carla.simms@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>, "Hawkins, Margaret" <margaret.hawkins@nara.gov>, "Rosen, Donald" <donald.rosen@nara.gov>, Evangela Wimbush-Jeffrey <evangela.wimbush-jeffrey@nara.gov>

Great news!! I'm glad we didn't jump to conclusions.

Jack Kabrel

Jack.Kabrel@nara.gov

Archives Specialist

National Archives and Records Administration

Permanent Records Capture Section

Cell (862) 686-7590

[Quoted text hidden]

Fwd: EPA Emergency Destruction Internal Concurrence

1 message

Anne Mason <marianne.mason@nara.gov>
To: Carla Simms <carla.simms@nara.gov>

Wed, Mar 25, 2020 at 10:41 AM

Hi Carla,

I should have copied you on this to keep you apprised of the situation, but I forgot. EPA will not be happy with this decision, as they were eager to destroy the records. This should be moving through the approval process this week if AOTUS isn't consumed with COVID19.

----- Forwarded message -----

From: **Anne Mason** <marianne.mason@nara.gov>

Date: Tue, Mar 24, 2020 at 8:17 AM

Subject: EPA Emergency Destruction Internal Concurrence

To: Lisa Haralampus <lisa.haralampus@nara.gov>

Cc: Darin Cote <darin.cote@nara.gov>, Jack Kabrel <jack.kabrel@nara.gov>, Pamela Najar-Simpson <pamela.najar-simpson@nara.gov>

Hi Lisa,

I contacted John Ellis and let him know that we would not be doing a site visit at this time due to the COVID19 situation. I feel we have enough information to move forward with the directing EPA to recover the records.

Attached is the internal concurrence memorandum recommending that NARA not approve the emergency destruction request. Additional attachments include the letter EPA sent to NARA, and email reply with more info from EPA, some photos of the damage, and a draft reply memo to EPA. Unless you have changes to either memo, the internal concurrence is ready to be moved through the approval process. Thank you,

--

Anne Mason, CA
Office of the Chief Records Officer, Operations Research and Support Team
Archives Specialist
301-837-3502
marianne.mason@nara.gov

--

Anne Mason, CA
Office of the Chief Records Officer, Operations Research and Support Team
Archives Specialist
301-837-3502
marianne.mason@nara.gov

7 attachments


IMG_0210.jpg
1525K



IMG_0216.jpg
2394K



IMG_0214.jpg
2193K

 **Emergency Destruction of Records OW2020-03-04-153128.pdf**
3119K

 **EPA-email.pdf**
122K

 **EPA 2020 Emergency Disposal Internal Concur Memorandum.docx**
64K

 **Reply to EPA Request for Emergency Disposal.docx**
65K