

Boston Medical Center Policy and Procedure Manual

Boston Medical Center HEALTH SYSTEM

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Section:	Materials Management

Sustainable Procurement Guidelines

Purpose:

To establish procurement guidelines regarding the health and environmental impacts of products and services when making purchasing decisions without compromising performance or affordability.

Policy Statement:

It is the policy of Boston Medical Center Health System (“BMCHS”) to consider in its procurement practices the social (worker rights and safety, fair trade), economic (innovation, local suppliers, supplier diversity) and environmental health impacts (greenhouse gas emissions, waste, chemicals/toxicity) throughout the life cycle of products and services in an effort to select safer and healthier products and services that are also environmentally sound. Products that have a lesser or reduced adverse effect on public health, workforce safety and the environment, when deemed affordable, should be prioritized over similar competing products or services that serve the same purpose.

Application:

All products and services purchased for use at BMCHS.

Exceptions:

Products used for research purposes.

Definitions (See Attachment D for additional terms and definitions):

1. **Circular Economy.** An economic model that aims to reduce waste and keep finite resources in use for as long as possible through reusing, refurbishing, repairing, and recycling.
2. **Renewable Materials.** Renewable materials are plant-based materials or materials that do not use up non-renewable resources, including but not limited to: biopolymers (e.g., corn, cellulose, starch, collagen based), bamboo, cork.
3. **Scope 1 Emissions.** Greenhouse gas emissions from sources that an organization owns or controls, such as fuel combustion or the use of anesthetic gases.
4. **Scope 2 Emissions.** Greenhouse gas emissions from the generation of energy that an organization purchases, such as electricity, steam, or heat.
5. **Scope 3 Emissions.** Greenhouse gas emissions from activities that are outside of an organization’s operational control but are a result of its actions. Purchased goods and services are often the largest category of an organization’s Scope 3 emissions.
6. **Take Back Program.** A program in which a manufacturer takes back a device for reprocessing and reselling, thereby extending the life cycle of the product.

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7. **Total Cost of Ownership**. The total cost to purchase, operate, and dispose of a product or service. This could include costs related to the safety of a product, workforce time required to use a product or service, and indirect ecological costs associated with a product.
8. **Workforce**. Employees, practitioners, volunteers, trainees, and other persons whose conduct in the performance of work is under the direct control of BMCHS, whether or not paid directly by BMCHS.

Procedure:

1. Procurement Guidelines

When making purchasing decisions, BMCHS will:

- a. Consider the environmental, social and health impacts of products and services as appropriate.
- b. Partner with suppliers and group purchasing organizations that demonstrate a commitment to sustainability through their business practices and can provide access to relevant data regarding the goods and services purchased, for example sustainable certifications, absence or presence of chemicals of concern, etc.
- c. Prioritize products that minimize or eliminate chemicals of concern (See Attachment A) in finished products, in the manufacture, process, use, and disposal of those products, and release little or no toxic by-products across their lifecycle. For example, prioritize furniture and furnishings without intentionally added flame retardants, PVC, formaldehyde, antimicrobials, and per- and poly-fluorinated compounds where regulatory and code requirements allow.
- d. Prioritize products that minimize the generation of waste over the life cycle of the product.
- e. Consider the greenhouse gas emissions impact of individual products, when appropriate, as well as the greenhouse gas reduction commitments and actions of distributors, manufacturers, and suppliers.
- f. Promote or increase use of products that are made from renewable materials.
- g. Purchase only latex-free and fragrance-free products.
- h. Select products or products with packaging that meet at least two of the nine waste and recyclability criteria in Attachment B.
- i. Support healthy food systems by sourcing healthy, local, sustainably certified, nutrition dense food products that minimize environmental health impacts.
- j. Collaborate with distributors, manufacturers, and suppliers in designing/refining products to minimize environmental impact while maintaining quality and cost effectiveness, with extra emphasis on the promotion of a circular materials economy, minimization of harmful chemicals, and the reduction of BMCHS's Scope 3 emissions:
 - i. Promote waste avoidance and reduction, including reducing packaging, recyclable packaging, and purchasing products that are reusable, recyclable and contain post-consumer recycled content.
 - ii. Promote circular economy principles and prioritize products that have dedicated supplier take back provisions.
 - iii. Support efficient transportation (e.g., cleaner fuel, streamlined routes) and related logistics.
 - iv. Conserve energy and water use in the manufacturing process; purchasing products that are energy and water efficient.

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- v. Promote land stewardship by protecting natural resources and cultivating healthy ecosystems.

2. Workforce Role

- a. Formally incorporate the criteria outlined in the Attachments into Requests for Information, Requests for Quotes, Requests for Proposals, Supplier Questionnaires and all activity aimed at supplier and/or product selection.
- b. Use the guidelines in the Attachments to:
 - i. Avoid purchasing products that contain chemicals of concern when alternatives are available.
 - ii. Purchase products that generate less waste over their life cycle than alternatives.
 - iii. Purchase products that generate fewer emissions over their life cycle than alternatives.
- c. Reduce BMCHS's total cost of ownership through the procurement process by considering costs beyond the purchase price.
- d. Facilitate discussions with internal Stakeholders regarding the environmental and human health impacts of the products and services prior to awarding contracts or selecting suppliers.
- e. Incorporate the criteria outlined in the Attachments in supplier management/business reviews to highlight importance for BMCHS to partner with like-minded suppliers and influence the marketplace to develop safer product and service offerings.

Responsibility:

Vice President, Supply Chain Operations

Attachments:

Attachment A: Procurement Criteria to Minimize Chemicals of Concern

Attachment B: Procurement Criteria to Minimize Waste

Attachment C: Procurement Criteria to Minimize Emissions

Attachment D: Terms and Definitions

Other Related Policies:

08.13.000 Procurement of Supplies, Equipment, and Services

References:

None

Initiated By:

Supply Chain Operations

Contributing Departments:

Supply Chain Operations

Support Services and Sustainability

Oakwell

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Attachment A

Procurement Criteria to Minimize Chemicals of Concern

Chemicals of Concern	Procurement Criteria	Resources
Antimicrobials (Preservatives)	Preferred products shall not contain any of the chemicals listed in GreenScreen Certified® Standard for Medical Supplies & Devices (v.1.0), Table A4 at greater than 0% (0 parts per million - ppm) in the product for the purpose(s) of preserving the product. (Adapted from GreenScreen Certified)	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.8 and Table A4 for list of prohibited antimicrobials
Antimicrobials (Surface Pathogens)	No antimicrobials allowed for use as a surface pathogen unless the manufacturer can provide a current US EPA registration as a public health antimicrobial pesticide product for the use pattern proposed with the full data required by 40 CFR Part 158 submitted to EPA. If claims against any specific public health microorganism are made, the registration must also include efficacy testing to reduce hospital acquired infections for each such microorganism. Note: conditional registration without a full data set is not acceptable. (Adapted from GreenScreen Certified)	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.7
Bisphenols, including Bisphenol A (BPA)	<p>Preferred products shall not contain homogeneous materials in products with any bisphenols (intentionally added, impurity or residual) $\geq 0.1\%$ by mass (1000 ppm) of the material listed in GreenScreen Certified® Standard for Medical Supplies & Devices (v.1.0), Table A2.</p> <p>Additionally, products are preferred that do not contain the broader list of Bisphenols specified in Clean Production Action's Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0 .</p>	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.2 and Table A2 for list of prohibited bisphenols • Clean Production Action, Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0
California Proposition 65 Chemicals	Preferred products do not contain chemicals listed by the State of California to cause cancer, birth defects, or reproductive harm that require a warning or are prohibited from release to the environment under the California Safe Drinking Water and Toxic Enforcement Act of 1986. Product threshold: the level of the chemical in the product is below the Proposition 65 labeling requirement. (Adapted from GreenScreen Certified)	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.6 • California OEHHA, The Proposition 65 List
European Union Restriction of Hazardous	Each electrical and/or electronic part in the product must be compliant with EU Directive 2011/65/EU and EU Directive 2015/863.22. This means each homogeneous material in each electrical and/or electronic part shall be	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0

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Substances Directive (EU RoHS)	compliant with all maximum concentration values excluding all exemptions. (Adapted from GreenScreen Certified)	see Annex 4, section A4.1 and Table A1 <ul style="list-style-type: none"> Access the regulatory list in Annex II of EU Directive 2015/863, which amends Article 4 of the RoHS Directive (2011/65/EU)
Halogenated flame retardants	<p>Preferred products shall not contain homogeneous materials in products (electronic and non-electronic) with any halogenated flame retardant chemical (intentionally added, impurity or residual) as defined below, which is $\geq 0.1\%$ by mass (1000 ppm) of the material.</p> <p>For Electronic products, this criterion applies only to product housing (the external enclosure or casing that protects the internal parts of a product, which includes a product stand and external power supplies).</p> <ul style="list-style-type: none"> Organohalogen: A chemical containing one or more halogen atoms (typically chlorine, bromine, fluorine, or iodine) bound to a carbon atom. Flame retardant: “Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire.” (Excerpt from California Senate Bill 1019, accessed 5/16/22) (Adapted from GreenScreen Certified) 	<ul style="list-style-type: none"> Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.4
Latex	Due to latex allergies, preferred products in high-risk categories such as surgical and exam gloves, catheters and other tubing, and sticky tape or electrode pads, do not contain latex.	
Non-halogenated flame retardants	Preferred products shall not contain homogeneous materials in non-electronic components with any non-halogenated flame retardant chemical (intentionally added, impurity or residual) $\geq 0.1\%$ by mass (1000 ppm) of the material as defined as: Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire, including but not limited to phosphorous-based and nitrogen-based chemicals. (Adapted from GreenScreen Certified)	<ul style="list-style-type: none"> Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.10
Metals and their compounds: Cadmium, Lead, Mercury, and Organotin	<p>Preferred products shall not contain homogeneous materials with mercury, lead, cadmium, or organotin and their related compounds (intentionally added, impurity or residual) in the following amounts:</p> <ol style="list-style-type: none"> Lead and lead-containing compounds $\geq 0.004\%$ by mass (40 ppm), Mercury and mercury-containing compounds $\geq 0.01\%$ by mass (100 ppm), Cadmium and cadmium-containing compounds $\geq 0.01\%$ by mass (100 ppm), and Organotin compounds [e.g., tributyltin (TBT), dibutyltin (DBT)] $\geq 0.01\%$ by mass (100 ppm). <p>(Adapted from GreenScreen Certified)</p>	<ul style="list-style-type: none"> Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.11

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Ortho-phthalates, including di(2-ethylhexyl) phthalate (DEHP)	<p>Preferred products shall not contain homogeneous materials in products with any ortho-phthalates (intentionally added, impurity or residual) $\geq 0.1\%$ by mass (1000 ppm) of the material that is listed in GreenScreen Certified® Standard for Medical Supplies & Devices (v.1.0), Table A3.</p> <p>Additionally, products are preferred that do not contain the broader list of ortho-phthalates specified in Clean Production Action's Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0 .</p>	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.5 and Table A3 for list of prohibited ortho-phthalates • For a detailed list of ortho-phthalates, see Clean Production Action, Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0
Per- and polyfluoroalkyl substances (PFAS)	<p>Preferred products shall not contain PFAS in each homogeneous material that are either a) intentionally added $\geq 0.01\%$ by mass (100 ppm) in each homogeneous material or b) an impurity $\geq 0.01\%$ by mass (100 ppm). See Attachment D, "Terms and Definitions," for definition of "PFAS."</p> <p>.</p>	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.12 • For a detailed list of PFAS see: Clean Production Action, Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0
Persistent, bio-accumulative and toxic chemicals (PBTs)	<p>Preferred products shall not contain homogenous materials with Persistent, Bioaccumulative, and Toxic chemicals (PBTs) (intentionally added, impurity or residual) $\geq 0.1\%$ by mass (1000 ppm) of the material, including chemicals on any of the following lists:</p> <ol style="list-style-type: none"> 1. US EPA—Priority PBTs and US EPA—Priority PBTs 2. OSPAR—Priority PBTs & EDs & equivalent concern 3. UNEP Stockholm Convention—Persistent Organic Pollutants 4. US EPA—Toxics Release Inventory PBTs 	<ul style="list-style-type: none"> • For a detailed list of PBTs see: Clean Production Action, Chemical Footprint Project (CFP) Chemicals of High Concern (CoHCs) Reference List v.3.0 • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.9
Polyvinyl chloride (PVC)	<p>Preferred products (electronic and non-electronic) shall not contain PVC $\geq 0.1\%$ by mass (1000 ppm) of the product. However, electronic cords, cables and connectors are exempted from this requirement.</p>	<ul style="list-style-type: none"> • Clean Production Action, GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, see Annex 4, section A4.3

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Attachment B

Procurement Criteria to Minimize Waste

Adapted from Clean Production Action, [GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0, section 8.1 Waste and Recyclability Criteria](#)

Products	Procurement Criteria	Resources
1. Hazardous waste	Does not create hazardous waste: when used for its intended purpose, the product is not regulated as a state or federal hazardous waste (i.e., does not become or generate a hazardous waste product according to state or federal hazardous waste rules): 1. The California Department of Toxic Substances Control's (DTSC) hazardous waste regulations (California Code of Regulations (CCR) Title 22, Division 4.5), or 2. Resource Conservation and Recovery Act (RCRA) regulations (Code of Federal Regulations (CFR) Title 40, parts 239 through 282).	<ul style="list-style-type: none">• US EPA Resource Conservation and Recovery Act (RCRA) waste• California Dept of Toxic Substances Control defining hazardous waste
2. Recyclability: PRODUCT	PRODUCT is recyclable.	
3. Post-consumer recycled content: PRODUCT	PRODUCT contains 10% or more post-consumer recycled content.	
4. Recyclability: PACKAGING	PACKAGING is recyclable (both primary and secondary packaging).	
5. Post-consumer recycled content: PRIMARY PACKAGING	PRIMARY PACKAGING contains more than 10% post-consumer recycled content.	
6. Post-consumer recycled content: SECONDARY PACKAGING	SECONDARY PACKAGING contains more than 30% post-consumer recycled content	
7. Forest Stewardship Council (FSC)	Packaging is currently certified under one of the following FSC Certifications: 1. 100%—From well-managed forests, 2. Mix—From responsible sources, or 3. Recycled—Made from recycled material.	
8. Consumer-friendly recycling labels	Packaging label meets US Federal Trade Commission Green Guides specifications in 16 CFR Part 260: Guides for the Use of Environmental Marketing Claims § 260.12 Recyclable Claims	An example of a consumer-friendly label is the How2Recycle Label®
9. Reusability / End of Life	Product/packaging is multi-use, or has a manufacturer- or supplier-operated take-back program	

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Attachment C

Procurement Criteria to Minimize Emissions in the Supply Chain

The following expectations are in line with and informed by the [Climate Excellence Standard for health sector suppliers](#) published by the U.S. Health Care Climate Council

Standard	Supplier Expectations	Resources
Emissions Disclosure	Annual disclosure of Scopes 1, 2 and 3 emissions in line with Greenhouse Gas (GHG) Protocol, including disclosure on a recognized platform such as CDP	Greenhouse Gas (GHG) Protocol
Near-Term Target	Adoption of a science-based target to reduce Scope 1 and 2 emissions in line with a 1.5	Science Based Targets Initiative
Net Zero Target	Adoption of a science-based target to achieve net zero emissions by 2050 or sooner	Science Based Targets Initiative
Life Cycle Assessments	A product-level emissions analysis has been conducted	

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Attachment D

Terms and Definitions (adapted from GreenScreen Certified®)*

Term	Definition
Antimicrobial Pesticide	“Substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses, or fungi on inanimate objects and surfaces” (US EPA What are Antimicrobial Pesticides?).
Antimicrobial Pesticide Product, Non-Public Health	“Non-public health antimicrobial pesticide products are those products that bear a label claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of non-public health claims would include, but are not limited to, algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made” (US EPA Pesticide Registration Manual: Chapter 4 - Additional Considerations for Antimicrobial Products).
Antimicrobial Pesticide Product, Public Health	“Public health antimicrobial pesticide products are those products that bear a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment” (US EPA Pesticide Registration Manual: Chapter 4 - Additional Considerations for Antimicrobial Products).
Antimicrobials (Preservatives)	“A type of antimicrobial pesticide used as “a preservative (e.g., fungicide or insecticide) built in or applied as a coating only to protect the product. . . . In these cases, the pesticide is registered for the intended use, and the sole purpose of treatment is to protect the product itself. These pesticides are widely used in the manufacture of textiles, plastics, paper, adhesives and coatings” (US EPA Consumer Products Treated with Pesticides).
Antimicrobials (Surface Pathogens)	“A type of antimicrobial pesticide intended to control microorganisms infectious to humans in any inanimate environment. The more commonly used public health antimicrobial products include the following: sterilants, sporicides, disinfectants, sanitizers, germicides.” (Adapted from US EPA definition of Antimicrobial Pesticides)
Bisphenols	“Any chemical compound with the following characteristics: 1. All chemical compounds with a Tanimoto Coefficient of 0.9-1.0 (compared to Bisphenol-A CASRN 80-05-7). [Note: Tanimoto Coefficient as calculated using EPA’s CompTox Dashboard.] 2. Any chemical compound with a Tanimoto Coefficient of 0.8-0.9 is restricted until there are publicly available, valid in vitro or in vivo hazard data that enable evaluation of estrogen and androgen receptor agonism and antagonism. If a compound does not have significant endocrine disrupting potential, it is not included. 3. Chemical compounds with a Tanimoto Coefficient <0.8 shall be considered restricted if the compound: a) Has demonstrated endocrine disrupting potential (estrogen and/or androgen receptor agonism and/or antagonism) and is used as a functional substitute for BPA, or b) Is detected in environmental media or human biomonitoring studies and it is used as a functional substitute for BPA and publicly available hazard data to evaluate endocrine disrupting potential (estrogen and/or androgen receptor agonism and/or antagonism) are lacking.” (Source: GreenScreen Certified for Single-Use Food Service Ware & Thermal Paper , Version 1.2, September 2023; see definition for BPA analogs on page 4)

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	Bisphenol A (BPA) is on the EU REACH restricted substances list as well as on the California Proposition 65 list for developmental and reproductive toxicity for women.
Flame Retardant	“Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire. Flame retardant chemicals include, but are not limited to, halogenated, phosphorous-based, nitrogen-based, and nanoscale flame retardants, flame retardant chemicals listed as ‘designated chemicals; pursuant to Section 105440 of the Health and Safety Code, and any chemical or chemical compound for which ‘flame retardant’ appears on the substance Safety Data Sheet (SDS) pursuant to Section 1910.1200(g) of Title 29 of the Code of Federal Regulations.” (California Senate Bill 1019)
Hazardous Waste	“Materials or substances that are regulated in the US as a federal or state hazardous waste when disposed after used for its intended purpose where: <ol style="list-style-type: none"> 1. Federal hazardous wastes are substances or materials that are “listed” as hazardous wastes (per 40 CFR Subpart D) or that meet the “characteristic” of being a hazardous waste (per 40 CFR Subpart C); or contain hazardous materials or substances when disposed are regulated by other environmental laws (CERCLA, TSCA, Nuclear Waste Policy Act); and 2. State hazardous wastes are substances “listed” as hazardous wastes by State regulations (e.g., 22 California Code of Regulations Appendix X) or meet the ‘characteristic’ of hazardous waste under State toxicity criteria (e.g., 22 California Code of Regulations 66261.24, Characteristic of Toxicity).”
Homogeneous Material	“One material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.” (EU Directive 2008/98/EC)
Impurity	“An unintended constituent present in a substance as manufactured. It may, for example, originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance, it was not intentionally added. In most cases impurities constitute less than 10% of the substance.” (ECHA).
Intentionally Added	“Included to serve a desired function; not an impurity or a residual.”
Organohalogen	“A chemical containing one or more halogen atoms (typically chlorine, bromine, fluorine, or iodine) bound to a carbon atom.”
Ortho-Phthalates	“Dialkyl ortho-phthalates (or phthalate esters) have the general chemical structure shown to the left, where each R group only contains hydrogen and carbon either in a linear or branched chain or cyclic chain (Adapted from USEPA Phthalates Plan 2012)
Per- and polyfluoroalkyl substances (PFAS)	“A class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.” (SB 5135, Safer Products for WA ACT)
Post-Consumer Recycled Content	“Waste material generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product, which can no longer be used for its intended purpose” (US Green Building Council).
Primary Packaging	“The layer of packaging in immediate contact with the product.”

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Product	“A finished good composed of parts, homogeneous materials, and/or chemical substances. A product may function as part of another product. A product may be made of one or more homogeneous materials.”
Recyclable	“A product or package is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program for reuse or use in manufacturing or assembling another item, with recycling facilities for the item available to at least 60 percent of communities where the item is sold” (FTC Regulation).
Recycled Content	“Refers to the portion of materials used in a product that have been diverted from the solid waste stream. If those materials are diverted during the manufacturing process, they are referred to as pre-consumer recycled content (sometimes referred to as post-industrial). If they are diverted after consumer use, they are post-consumer” (Building Green Defining Recycled Content).
Residual	“Chemical or substance added upstream in the supply chain to serve a desired function: <ol style="list-style-type: none"> 1. In the additive or homogeneous material but not in the final product as placed on the market; or 2) In the production of the additive or homogeneous material. For example, this may refer to substances included in a manufacturing process to aid processing, as well as inputs to a reaction process such as reagents, catalysts, monomers, or preservatives for raw materials.”
Secondary Packaging	“Protects the product and the primary packaging. An example of secondary packaging is a cardboard box or plastic crate containing multiple products in primary packaging.”

*Source: Unless otherwise noted, all terms and definitions are from: Clean Production Action, [GreenScreen Certified® Standard for Medical Supplies & Devices, v.1.0](#), “Terms and Definitions”