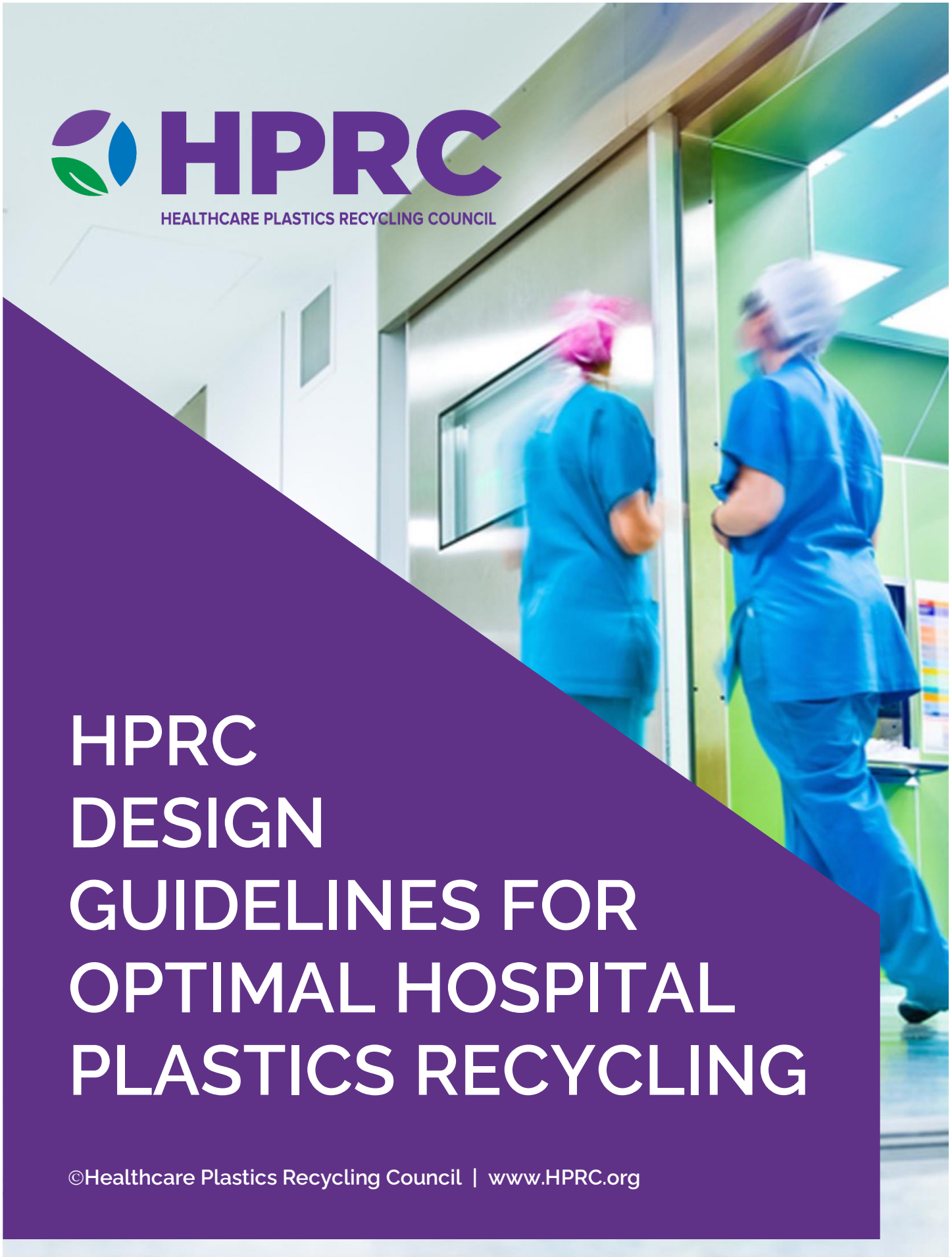

HPRC

HEALTHCARE PLASTICS RECYCLING COUNCIL

HPRC DESIGN GUIDELINES FOR OPTIMAL HOSPITAL PLASTICS RECYCLING

CONTENTS

INTRODUCTION

This guidance aims to influence the design of plastic healthcare products and packaging for improved recyclability without deteriorating product integrity or performance. This guidance provides recommendations for preferred materials for mechanical recycling processes and briefly describes potential future opportunities for the use of advanced recycling technologies. This guidance has been updated from the previous, 2016 version based on current trends, technology advancements, and the expanded membership of the Healthcare Plastics Recycling Council (HPRC).

Design for Circularity

The focal point of this guidance is recyclability. However, in alignment with the waste hierarchy, sustainable product and packaging design should first prioritize reduction and reuse. Reduction may entail the use of fewer materials, the use of more environmentally preferred materials, or avoidance of the product or packaging altogether. Product or packaging reuse may reduce waste and create resource efficiency by allowing for a product or packaging to be used many times before reaching the end of its useful life. Prioritization in accordance with the waste hierarchy supports the principles of a circular economy, which aim to eliminate waste and keep materials in use as long as possible.

Recyclability Definitions and Claims

By definition, a product or package may be deemed recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program for use or reuse in the manufacturing of a new product. However, due in part to geographic variability in recycling facility access, recyclable products and packaging will not always be recycled. While many materials may be technically or chemically suitable for recycling, access to the appropriate recycling facilities is a common barrier. In order to address this challenge, the U.S. Federal Trade Commission Green Guides specify that in order to make an unqualified recycling claim, recycling facilities must be available to at least 60% of the market where the product/packaging is sold.[1]

The Ellen MacArthur Foundation, with similar intent, has proposed that product packaging be recyclable both 'at scale' and 'in practice' in order to make recyclability claims.[2] Criteria vary from region to region, and new legislation continues to emerge regarding recyclability claims.[3] This guidance document does not include in-depth coverage of the regulatory context, but legal aspects should always be reviewed and considered in the sustainable product and packaging development process.

Additional Considerations

Beyond recyclability claims and available recycling technologies, product development and design teams should also consider the needs of hospital operations. Healthcare facility storage space, logistics, and personnel may impact the feasibility of material separation for recycling or reuse. Consideration of the product's overall environmental impact, which can be determined using life cycle assessment (LCA), is also recommended.

We hope that this guidance will raise awareness of good design practices to improve recyclability as well as educate and inform design teams of practices to avoid that may hinder plastics recyclability. These guidelines may also benefit hospital staff, waste haulers, and recyclers interested in the effective recycling of healthcare plastics.

SOURCES OF PLASTIC PACKAGING & PRODUCT DESIGN GUIDANCE

Several plastic recycling organizations have developed guidance materials aimed at increasing plastic recyclability through improved plastic packaging and product design. This section provides an overview of four contributing organizations and the design resources they have available to incorporate improvements in plastic packaging and products.

The Association of Plastic Recyclers (APR)

APR is an international trade association representing the plastics recycling industry. APR's Design® Guide provides package designers with recommendations and guidance based upon the collective expertise of the North American plastics recycling industry. The guide is accessible without a login on APR's website where it is regularly updated as recycling technology evolves, and new packaging innovations emerge. The guide is organized by the polymer type of the packaging application.

APR's Design Guide is organized by design features, such as color and material selection. Each design feature is classified as Preferred, Detrimental to Recycling, Renders Package Non-Recyclable, or Requires Testing based on its impact on recyclability. Note that Detrimental to Recycling is still recyclable per the definition of recyclability. The terminology is intended to promote improvement. Designers are advised to prioritize preferred features and avoid features that render a package non-recyclable whenever possible.

APR has additional resources available to packaging designers to help confirm the compatibility of a packaging application with the recycling technology in the market. Organizations can leverage APR's Critical Guidance Recognition and Meets Preferred Guidance programs to confirm the recyclability of their packaging technology. APR has developed rigorous testing protocols based on packaging and polymer type to enable these determinations.

A critical note for designers of healthcare packaging: Some commonly used polymers and formats are not specifically listed in APR's Design Guide due to the lack of a robust national market and recycling infrastructure for these formats. When confronted with this situation, design teams should consider the use of a more readily recyclable polymer type. APR continuously monitors and updates the tool as new recycling markets develop.

RecyClass

RecyClass is a non-profit, cross-industry initiative focused on advancing plastic packaging recyclability and ensuring traceability and transparency of recycled plastic content in Europe. RecyClass' Design for Recycling Guidelines provides recommendations for common packaging formats based on compatibility with

the European plastics recycling industry. The tool is continuously reviewed and updated based on the latest technology and market developments and is accessible on the RecyClass website.

Using a survey format, the RecyClass tool requests that packaging designers respond to a series of design-related questions pertaining to a specific packaging design. These questions collect information about key design attributes that influence a package application's recycling compatibility. Designers have visibility into the impact of their answers on the interim result as they progress through the survey. The tool calculates a final assessment at the conclusion of the survey, with grades ranging from A to F. An "A" grade indicates the best recyclability performance of a package, while an "F" grade indicates that the package is not recyclable. The results of the RecyClass tool survey include a summary of Design for Recycling incompatibilities as well as a map that indicates which European countries have the appropriate infrastructure to sort, collect, and/or recycle the design in question. Design for recycling recommendations behind the RecyClass tool are based on scientific evidence. RecyClass developed and published standard recyclability and sorting evaluation protocols to assess the compatibility of substances and components in plastic packaging. Test campaigns are yearly funded by RecyClass to accelerate the transition to circular design for recycling criteria and to contribute to the European standardization of such design criteria.

RecyClass provides additional resources to packaging designers seeking to certify the recyclability of the packaging application. The Certification Scheme developed by RecyClass offers three types of recyclability assessments: Design for Recycling Assessment, Recyclability Rate Assessment, and Letter of Compatibility. Certifications are also available for the use of Recycled Plastics and Recycling Processes.

A critical note for designers of healthcare packaging: there are examples of commonly used polymers and formats not available for assessment in the tool. In these instances, the RecyClass tool concludes the assessment process and provides a grade of "F" due to the lack of a robust market and recycling infrastructure for these formats. RecyClass continuously monitors and updates the tool as additional markets for new materials develop.

Circular Economy for Flexible Packaging (CEFLEX)

CEFLEX is a consortium of European flexible packaging industry stakeholders that aim to tackle industry barriers to a circular economy. As a part of this initiative, CEFLEX has developed a set of Designing for a Circular Economy resources for polyolefin-based flexible packaging, based on existing European sorting and mechanical recycling processes. The guidelines include recommendations for packaging consisting of polyethylene (PE), polypropylene (PP), or mixes of these polymers. These resources were developed through the collaborative efforts of packaging converters, film producers, brands, and recyclers and are available on

the CEFLEX guidelines website. Updates will be incorporated as testing data is completed for defined materials that are not currently widely sorted or recycled.

The CEFLEX Designing for a Circular Economy Guidelines Technical Report provides detailed design principles and best practice guidelines for material selection, as well as end-of-life information related to collection, sorting, and recycling processes. Material thresholds are summarized in tabular form for polyolefin-based flexible packaging based on the categories Compatible, Limited Compatibility, and Not Compatible with mechanical recycling infrastructure. CEFLEX also has available a table for "Materials and their Properties" as an overview of key materials that are used for flexible packaging including their properties and uses.

In addition, CEFLEX developed a webinar series titled "Designing for a Circular Economy - In Action" to showcase examples of how the guidelines have been adopted by users.

CEFLEX guidance was developed specifically for consumer product flexible packaging, but the design guidance and principles may be applicable to healthcare packaging made from polyolefin polymers. CEFLEX aims to continue aligning their package design guidance with similar organizations as recycling infrastructure and recommended materials evolve.

Sustainable Packaging Coalition (SPC)

The U.S.-based Sustainable Packaging Coalition (SPC) is a membership-based collaborative that brings together sustainable packaging industry stakeholders to drive improvements in packaging systems. The SPC Design for Recycled Content Guide provides key considerations for the use of recycled content and how to design packaging that incorporates recycled materials and is available on the SPC website. In addition, the SPC Guide provides critical details about the current and projected change in demand for specific types of recycled materials, which serves to further inform responsible design choices based on recycled material supply. The SPC guidance focuses on commonly used packaging materials, such as polyester (PET), high density polyethylene (HDPE), PP, polystyrene (PS), paper, glass, and aluminum. It also provides guidance on the use of these materials for consumer products in the food industry and consumer healthcare space.

The SPC guidance was developed with a focus primarily on the use of post-consumer recycled content within the North American context. However, many key insights could be applicable to post-industrial recycled content and may also be valuable and appropriate in other regions. The dynamic, web-based guide was launched in 2018 following SPC interviews conducted across the value chain, and it is updated regularly based on SPC member, collaborative, and industry input. Considerations could be added specific to healthcare as SPC's membership demographic, recycling technology, and regulatory landscape evolve.

SPC and its parent organization, GreenBlue, offer additional resources for design for recyclability guidance, recyclability labeling, and recycled material certification. These include the How2Recycle program that has developed a user-friendly labeling system with clear instructions for consumers on the appropriate disposal of packaging materials. How2Recycle is designed for companies to label consumer-facing packaging that is likely to be disposed of at home or where curbside recycling and drop-off programs exist. Due to the differences in access, collection, and local procedures, the label is not currently designed to support products that end up in healthcare facilities. In addition, the How2Recycle Guide for Recyclability provides insight into how the How2Recycle program assesses recyclability on a package-by-package basis and how the Recycled Material Standard (RMS) Certification program supports recycled material claims.

The following table provides a comparative summary of key attributes of each external organization. It is important to note that these guidelines were not crafted to be inclusive of healthcare packaging given the nascent state of recycling at healthcare facilities. However, the best practices identified in these guidelines are anticipated to be applicable to healthcare packaging as recycling systems mature.

	APR	RECYCLASS	CEFLEX	SPC
Rigid vs. Flexible	Rigid and Flexible	Rigid and Flexible	Flexible	Rigid and Flexible
Product/ Package Type	Packaging: Plastics (PET, HDPE, PVC, PE film, PP, expanded polystyrene (EPS), PS, and polylactic acid (PLA))	PET bottles, PET trays, HDPE and PP containers and tubes, EPS containers, PE and PP films, PS colored containers, and HDPE and PP crates and pallets	Polyolefin-based flexible packaging	Packaging: Plastics (PET, HDPE, PP, PS, and PE film), paper (paperboard, corrugate), glass, aluminum, and steel
Applicable Region	North America	Europe	Europe (guidance can be broader)	Primarily the U.S. and Canada (though many elements of the guidance are applicable in other regions)
Website	http://plasticsrecycling.org/apr-design-guide	https://recyclass.eu/recyclability/design-for-recycling-guidelines/	https://guidelines.ceflex.eu/	https://recycledcontent.org/
Offers Testing/ Certification	Critical Guidance Recognition, Meets Preferred Guidance, and Post-Consumer Recycle Material Certification	RecyClass Recyclability Certification, Recyclability Approvals - Technology Approval and Product Approval, RecyClass Recycling Process Certification, and Recycled Plastics Traceability Certification	None	Recycled Material Standard Certification
Guide or Tool Names	APR Design® Guide	Web-based resources: RecyClass Online Tool; Design for Recycling Guidelines; and RecyClass Design Book: A Step-by-Step Guide to Plastic Packaging Recyclability	Downloadable documents: Designing for a Circular Economy: Guidelines Summary; Designing for a Circular Economy: Recyclability of polyolefin-based flexible packaging Executive Summary and Designing for a Circular Economy: Recyclability of polyolefin-based flexible packaging Technical Report, June 2020	Design for Recycled Content Guide
Additional Resources	APR Design® Guide Training Program	Downloadable documents: Recyclability & Sorting Evaluation Protocols, RecyClass Quick Test Procedures, and PET packaging-specific evaluation protocols and test procedures	Designing for a Circular Economy: Materials and their properties table (June 2020)	How2Recycle label, How2Recycle Guide for Recyclability

PRODUCT & PACKAGING GUIDANCE

Packaging Guidance

This guidance is intended to provide information about materials and formats for use in the design of plastic medical device packaging and products. In particular, the details within this section will outline materials that are preferred and less preferred for mechanical recycling.

This guidance is not intended to classify certain materials and formats as recyclable or not recyclable at scale. Materials and formats that are not recyclable at scale may still be preferred for use in medical device packaging because they are technically recyclable or advance the recyclability of the package.

The tables contain design guidance for the most frequently used plastic packaging formats in medical device packaging. However, this guidance should not be considered comprehensive and does not include all packaging formats and materials used in medical device packaging.

Design criteria and material or format selection that ensure product quality, product safety, efficacy, stability, and protection should always supersede these Design for Recyclability Guidelines.

Classifications

Within this section, packaging materials and formats are classified by preferred design aspects, based on qualities that facilitate recyclability:

HEALTHCARE PREFERRED	HEALTHCARE LESS PREFERRED	HEALTHCARE NOT PREFERRED
Preferential material or design option that optimizes recyclability.	Less preferred material or design option that does not optimize recyclability yet has been proven to consistently meet product safety requirements. Consideration should be taken to transition to a Healthcare Preferred option when product safety can be matched or exceeded.	Material or design option that does not optimize recyclability and should be avoided when possible.

RIGID THERMOFORMED BLISTERS AND TRAYS

	MATERIAL	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	PET HDPE PP	Lightly tinted translucent/transparent blue (PET) Natural (no tint)	Embossing Direct print
HEALTHCARE LESS PREFERRED	Polyethylene terephthalate glycol (PETG)	White Transparent colors	Polyolefin label (PE or PP)
HEALTHCARE NOT PREFERRED	Other materials (e.g., PVC, PS, thermoplastic polyurethane (TPU), mixed materials) Heat seal coatings, direct seal sealants, or coextruded sealing layer	Dark or opaque colors	Paper label Other plastic label substrates

POROUS LIDDING

	MATERIAL	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	HDPE nonwoven	Natural or white	Direct Print
HEALTHCARE LESS PREFERRED	Paper		Polyolefin label (PE or PP) Paper Label Match substrate being applied when possible
HEALTHCARE NOT PREFERRED	Other, non-polyolefin materials	All other colors	Other plastic label substrates

NON-POROUS LIDDING

	MATERIAL	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	PE coextrusion (HDPE, LDPE, etc.) PE lamination PP PET with density >1	Natural or white	Direct Print
HEALTHCARE LESS PREFERRED	PET with density <1		Polyolefin label (PE or PP) PET label Match substrate being applied to when possible
HEALTHCARE NOT PREFERRED	Mixed plastics or multi-material lamination Foil lamination	All other colors	Paper Label Other plastic label substrates

HEADER BAGS AND VENT BAGS

	MATERIAL *(bag)*	MATERIAL *(header/vent)*	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	PE coextrusion (HDPE, LDPE, etc.) PE lamination	HDPE nonwoven	Clear, natural, or white	Direct Print
HEALTHCARE LESS PREFERRED	PP/ PE coextrusion PP/ PE laminations Nylon/ PE coextrusion Nylon/PE laminations	Paper		Polyolefin label (PE or PP) Paper label Match substrate being applied to when possible
HEALTHCARE NOT PREFERRED	Mixed plastics or multi-material lamination Foil laminations	Other non-polyolefin materials	All other colors	Other plastic label substrates

POUCHES: POROUS

	POROUS/ BREATHABLE MATERIAL	NON-POROUS FILM MATERIAL	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	HDPE nonwoven	PE coextrusion (HDPE, LDPE, etc.) PE laminations	Clear, natural, or white	Direct Print
HEALTHCARE LESS PREFERRED	Paper	PP/ PE coextrusion PP/ PE laminations Nylon/ PE coextrusion Nylon/ PE laminations PET/ PE laminations		Polyolefin label (PE or PP) Paper label Match substrate being applied to when possible
HEALTHCARE NOT PREFERRED	Other non-polyolefin materials	Other multi-material laminations Foil laminations	All other colors	Other plastic label substrates

POUCHES: NON-POROUS (FILM TO FILM)

	MATERIAL	COLOR	REQUIRED INFORMATION *(e.g., lot codes, expiry dates)*
HEALTHCARE PREFERRED	PE coextrusion (HDPE, LDPE, etc.) PE laminations	Clear, natural, or white	Direct Print
HEALTHCARE LESS PREFERRED	PP/ PE coextrusion PP/ PE laminations Nylon/ PE coextrusion Nylon/ PE laminations PET/ PE laminations		Polyolefin label (PE or PP)
HEALTHCARE NOT PREFERRED	Other non-polyolefin materials Foil laminations		Paper label Other plastic label substrates

FLEXIBLE FORM FILM SEAL: BOTTOM WEB

	MATERIAL	COLOR
HEALTHCARE PREFERRED	PE coextrusion (HDPE, LDPE, etc.)	Clear, natural, or white
HEALTHCARE LESS PREFERRED	Ionomer coextrusion* Nylon/ PE coextrusion PP/ PE coextrusion	
HEALTHCARE NOT PREFERRED	Other multi-material coextrusions	All other colors

For lidding materials (top web), see porous and non-porous lidding tables above.
*Reference the APR Design© Guidance for further details

BARRIER MATERIALS (FOIL AND METALLIZED FILMS)

	MATERIAL
HEALTHCARE PREFERRED	Barrier coatings (SiOx and AlOx)* Metallized polyolefin laminations (metallized PP, metallized PE)
HEALTHCARE LESS PREFERRED	Low gauge foil laminations Metallized PET laminations
HEALTHCARE NOT PREFERRED	High gauge foil laminations

*Reference the APR Design© Guidance or RecyClass guidance for further details on barrier coatings

In general, the following practices may be applied (or avoided) when designing polymer-based packaging and/or products:

Preferred Design Practices

- Design with mono-materials, where possible.
- Use of materials that can be easily separated for appropriate disposal, particularly when dissimilar materials are required (for example, combinations of materials with densities < 1 and > 1 like PET and HDPE since PET will sink and HDPE will float during recycling process).
- Use of breathable plastics as an alternative to paper.
- Minimization of paper labels and components.
- Use of recycle friendly or water releasable adhesives.
- Minimization of inks.
- When multiple materials are required, use chemically compatible or jointly processable plastics, such as PP and PE.
- Use of polyolefin seals or gaskets on polypropylene bottles.

- Bottle and bag design that facilitates easy and complete drainage of contents prior to disposal.
- Communication to end-users allows for easy identification of residual liquids.

Less Preferred Practices

- Use of a rubber seal on propylene bottles that will sink in water.
- Designs that combine chemically incompatible biobased or biodegradable plastics with petroleum-based plastics, for example, PLA and PET. Different types of plastics combined through processes that hinder separation, such as welding, gluing, lamination, or molding.
- Plastic films combined with paper in packaging.

Not Preferred

- Lead use.
- PVC use.
- The use of metal screws or grommets in plastic.

LABELING

Desirable Labeling Design Practices

This section intends to provide guidance on the two general areas listed below and is meant to cover package labeling, not device labeling:

- Package labeling design guidelines which may allow for improved recyclability.
- Package marking, including the use of symbols and text which may aid in the education of the consumer on proper recycling of the packaging.

Label Design Guidelines

Labels are an integral part of the packaging system and often serve as the communication function for the packaging. A packaging system may require multiple labels to properly communicate appropriate product information.

However, labels on plastic components can become a contaminant to the recycling stream. For common sterile barrier materials, it is preferrable to use a material that is compatible with the recycling stream best fit for the package system and to reduce the size of the label when possible.

In addition to the proceeding guidance, further labeling coverage guidance can be found in the aforementioned APR, RecyClass, and CEFLEX guidance documents.

Reduce Label Size and Quantity

- Select a properly sized label for the label content. Figure 1 shows a label that is unnecessarily oversized.
- Avoid the placement of unnecessary communication on the label to facilitate optimized label sizing.
- Consider alternative communication methods for information that is not required on the package label, such as inclusion in the instructions for use (IFU) or the use of QR codes.
- Avoid using multiple labels on the same package component. Figure 2 shows a package with multiple labels.
- When labeling opaque materials, consider printing directly on the substrate during the packaging process instead of using a label. This method is typically used during form-fill-seal packaging operations. Figure 4 shows a package with direct printing applied.
- Utilize pre-printed packaging components. Packaging suppliers typically have printing capabilities and can provide materials with product information already printed on the components (e.g., product description, part numbers, manufacturing location). Figure 5 shows a package with pre-printed Tyvek® and a supplemental label.

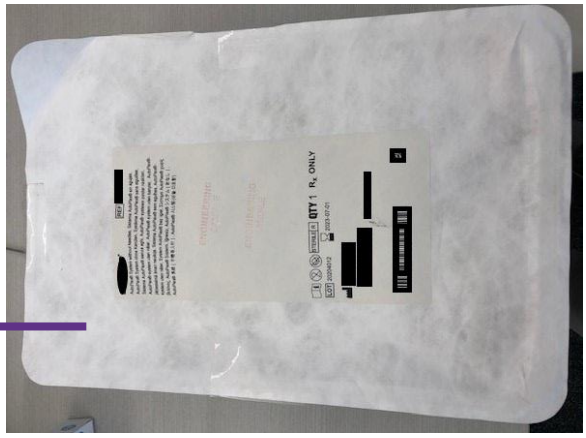

Figure 1.
Package with Oversized Label – Not Preferred

Figure 2.
Package with Multiple Labels – Not Preferred

Figure 3.
Package with Paper–Based Label – Not Preferred

Figure 4.
Tyvek with Direct Print (no label) – Preferred

Figure 5.
Pre-Printed Tyvek – Preferred

Consider Label Placement

- For labels that are not compatible with the optimal recycling stream for the package, it is best practice to place labels on the component that is least likely to be recycled and/or the component with the least amount of recyclable material.
- Consolidate labels to one specific packaging component. For instance, if the packaging design consists of a rigid thermoformed tray with a Tyvek lid, avoid placing labels on both packaging components. Affix all labeling to the Tyvek lid (note: consider sterilization limitations that may apply).

Use Label Substrate Materials, Inks, and Adhesives Preferred for Recycling

- Label Substrate Selection

    - For plastic components, polymer-based labels are preferred over paper-based labels. Paper-based labels can pulp during mechanical recycling wash processes and may result in significant recycling inefficiencies. Figure 3 above shows a plastic package with a paper-based label.
    - In general, labels should be made from the same material as the substrate they are being applied to, especially when the substrate is a commonly recycled material. Exceptions to this approach can be found in the tables within the 'Product and Package Guidance' section of this document.
- Label Ink Selection
    - Avoid petroleum-based inks due to the high volatile organic compound content.
    - Avoid the use of restricted substances such as cadmium, lead, mercury, and hexavalent chromium.
- Label Adhesive Selection:
    - When label substrate is not preferred for recycling with the component it is attached to (e.g., a paper label on a PE film component), use water-soluble adhesives, when possible, which allow for easier separation of the label from the substrate during the mechanical recycling process.

Note: For additional guidance on label design criteria for specific packaging components, please refer to the 'Product and Package Guidance' section of this document.

Package Marking Guidance

Previous HPRC pilot studies have shown that proper consumer education at the point of disposal is a significant factor in the efficacy of plastic packaging recycling. The proper use of recycling symbols and other user-friendly package markings can greatly improve recycling efforts.

Unfortunately, there is currently no harmonized system for medical device and package marking to indicate recyclability. The lack of a standardized collection and recycling process, risk of contamination, and challenges with sorting of materials at point of use are a few factors that contribute to this. This leaves identification of the material the component is made of as one of the only options for on-package marking guidance. Today, one of the most common options for identifying the material a plastic component is made of is through a Resin Identification Code (RIC).

RIC symbols are markings that typically appear as a number enclosed in chasing arrows or an equilateral triangle and are used on plastic packaging to indicate the type of plastic resin the material is composed of. RIC symbols are commonly applied to rigid packaging components by embossing as part of the component tooling design. Although RIC symbols give information about the type of plastic used, they are not intended to indicate the recyclability of the material. Nonetheless, RIC symbols are often misinterpreted by consumers and understood to be a recycling symbol or indication of recyclability. This common misunderstanding can lead to improper disposal of non-recyclable materials, which may in turn contaminate recycling streams.

Follow American Society for Testing and Materials (ASTM) D7611 for appropriate use of RIC symbols:

- Do not use RIC symbols as an indicator of recyclability.
- Ensure that recyclability of the final packaging product is clearly understood and appropriately communicated to the end user for proper disposal whenever possible.
- Review country/state/regional legislation to ensure appropriate integration of RIC-related requirements. For instance, according to requirements within the state of California, the No. 1 RIC symbol must not be applied to PETG materials.

Resin Identification Number	Resin	Resin Identification Code –Option A	Resin Identification Code –Option B
1	Poly(ethylene terephthalate)	1 PETE	01 PET
2	High density polyethylene	2 HDPE	02 PE-HD
3	Poly(vinyl chloride)	3 V	03 PVC
4	Low density polyethylene	4 LDPE	04 PE-LD
5	Polypropylene	5 PP	05 PP
6	Polystyrene	6 PS	06 PS
7	Other resins	7 OTHER	07 O

Figure 6. Resin Identification Codes as defined by ASTM D7611-21[4]

When a medical package or device is used in a consumer setting as opposed to a healthcare facility, or where local recycling guidelines allow, user-friendly package marking for recycling can be defined with symbols or instructions on how to properly dispose of the packaging material or devices within.

For guidance and alignment on the proper use of symbols, please refer to guidance from the organizations in the 'Existing Sources of Plastic Packaging and Product Design Guidance' section of this document.

Note: Consult with legal and/or regulatory authorities for proper application of any type of symbols used on medical device packaging.

In summary, when developing labels designers should aim to reduce the overall volume of label material required. When no further material reduction is possible, designers should select more readily recyclable materials. Recycling techniques, package marking requirements, and sustainable materials continue to evolve and may have an impact on label and packaging marking selection. It is highly recommended to research the latest trends in sustainable design for labeling before committing to the design criteria prescribed in this document.

USE OF RECYCLED MATERIALS

The use of recycled materials in medical device packaging is a topic that continues to gain interest in the healthcare industry. In order to reach the end goal of a truly circular system, recycled content will eventually need to be used in healthcare packaging to some extent. There are two types of recycled content that can be considered for use in medical packaging:

- Post-Consumer Recycled Content (PCR)
- Post-Industrial Recycled Content (PIR)

PCR material is defined in ISO 14021:2016(en) Environmental labels and declarations as material produced by consumer households or in commercial, industrial, and institutional applications where the material has reached its end use and can no longer be used for its intended purpose.

PIR materials, or pre-consumer materials, are defined in ISO 14021 as materials diverted from the waste stream during a manufacturing process. There is an exclusion for materials considered as rework, regrind, or scrap that were produced during manufacturing and could be reclaimed within the same process.[5] Typically, manufacturers collect scrap plastic material from the beginning or end of a process and, with minimal processing, mix the pure scrap material and re-grind with virgin material. As this is normal practice, and therefore the scrap material would not enter the waste stream during standard production, the use of scrap in this manner is not considered recycling. However, if the manufacturing processes prevent scrap material from being used as feedstock, but the material can be used in the production of an alternative product and would otherwise be waste, this may be considered recycling.

Advanced Recycled Materials

Advanced recycled materials are materials created through advanced recycling technologies, which can include both PCR and PIR. Advanced recycling is a suite of novel recycling techniques including pyrolysis, gasification, depolymerization and dissolution, intended to complement mechanical recycling by focusing on materials that are difficult to recycle with the current mechanical recycling infrastructure. The processes typically involve reverting plastic waste materials to their original building block molecules, or purifying the polymer materials, then using these molecules to create new polymers. This is done through the use of chemical solvents and/or heat and pressure.

Because advanced recycling processes revert waste plastics back to pure polymer feedstocks that are indistinguishable from virgin fossil feedstocks, the final polymer is the same composition as that made from virgin fossil feedstocks alone. There is no analytical measurement to differentiate between materials made with waste plastic resources and materials made with virgin fossil resources. Consequently, to promote transparency it is important to have appropriate tracking of recycled content throughout each step in the manufacturing process including supply, production, and conversion.

It is common practice in advanced recycling to mix recycled material feedstock with virgin materials, additives, fillers or masterbatches during production to meet client specifications. In order to provide traceability of the recycled content during material production, a mass balance approach certified by a third party such as ISCC PLUS, RMS, UL, RSB, GRI, or others is used, with ISCC PLUS being the most

common at the current time. By using a certified mass balance approach, each step of the manufacturing process can verify how much recycled material was used in production and ensure the recycled content is appropriately accounted for in the final product.

Use of PCR

Preferred when regulatory and performance constraints allow.

PCR materials are not well-suited for primary packaging of sterilized medical devices today due to ISO 13485 traceability requirements. However, PCR materials can be used in secondary and tertiary packaging that is not part of the sterile barrier system. Appropriate uses of PCR content include corrugated shipping boxes, stretch wrap film, paper cartons, or secondary overwraps that are not part of the sterile barrier system.

Furthermore, some applications for non-sterile healthcare products are not required to meet the ISO 13485 requirements. In these specific cases, a U.S. Food and Drug Administration (FDA) approved PCR material could be considered for use in the primary packaging. It is important to ensure the physical property requirements and biocompatibility requirements are met with PCR materials when being considered for these specific applications.

The Blue Renew Program, a partnership between Owens and Minor and Halyard Health, is a leading example of how PCR from polypropylene-based blue wrap is recycled and repurposed within the healthcare industry today. Surgical blue wrap, used to cover sterile surgical instruments, is collected at hospitals, picked up by a local waste hauler, and sent to Owens and Minor for reprocessing into BlueCON resin. After reprocessing, the resin is used to produce other common hospital items such as trash bins, recycling bins, and bedside pans.[6]

As recycling becomes more important to the healthcare industry, it is likely that similar partnerships like Blue Renew may emerge.

Use of PIR and Reutilization of Materials

Recommended where post-consumer recycled content cannot be used.

PIR materials that are reprocessed offsite can be used freely in secondary and tertiary packaging for healthcare products. Since this material is often leaving the manufacturing facility to be reprocessed and may be combined with feedstock from other sources, it is not recommended to use PIR materials as defined in ISO14021 in primary packaging for healthcare applications.

Although it is not considered recycled content, the reutilization, or reuse of scrap materials during a manufacturing process, can be implemented in primary

packaging of medical devices today as long as the proper quality assurance and mechanisms for traceability are in place. With safety as the top priority, it is important to work with the material supplier to ensure a consistent percentage of scrap material can be added back into the manufacturing process without compromising the quality of the final product.

The ISO TIR 65: 2015 standard for medical device sustainability, developed by the Association for the Advancement of Medical Instrumentation (AAMI), recommends the reuse of scrap material during manufacturing of materials for healthcare applications because it can meet traceability requirements. In particular, in-process re-grind can be valuable for use in sterile barrier packaging because it uses material from the same lot, which is easily traceable.[7]

There are no regulatory requirements specific to the reuse of scrap materials. In most cases, the supplier will use quality assurance data to show the product's critical attributes will remain within the specification limits when in process re-grind or scrap material is incorporated during processing. Consequently, the selection of a trusted and certified supplier with sound quality control measures in place is critical for appropriate use of these materials within the healthcare industry.

Use of Advanced Recycled Content

Continue to monitor development and scaling of new technologies.

Advanced recycling is an evolving technology within the plastics industry. There are many different technologies for advanced recycling of materials with more continuing to emerge. For this reason, many of the regulatory qualifications for advanced recycled plastics in healthcare packaging are still underway. With that in mind, the products of advanced recycling technologies continue to gain interest especially as a means to incorporate recycled content in medical packaging.

As it stands today, one of the main challenges behind incorporating advanced recycled content in medical packaging is that regulatory organizations, such as the FDA in North America and the European Medicines Agency (EMA) in Europe, have not yet completed an extensive review of these materials or firmly established their fitness for use in medical applications. Given the high level of complexity and varied processes associated with advanced recycling, thorough investigation and evaluation will require substantial effort from regulatory bodies before they are able to release a formal statement on the suitability of these materials in the industry.

Furthermore, the energy requirements and greenhouse gas emissions associated with advanced recycling have raised concerns about the environmental impacts of advanced recycled plastics. Environmental impacts vary depending on the

material supplier and the type of advanced recycling technology used. Based on existing data, it is understood that mechanical recycling technologies have a lower environmental impact overall compared to pyrolysis processes.[8]

However, resins produced from advanced recycling do not require raw material extraction like their virgin resin counterparts and tend to use less water during material production. Therefore, the production of resins from advanced recycling technologies may have a lower environmental impact than materials produced from virgin resin feedstock. Advanced recycling processes also allow for a wider range of inputs than mechanical recycling processes, accommodating materials that may have been landfilled or incinerated without an advanced recycling option. When compared to the alternative of incineration, a recent independent study concluded that advanced recycling of mixed plastic waste can emit up to 50% less carbon dioxide.[9]

Challenges in Incorporating Recycled Content

When considering the preceding guidance, it is important to recognize some of the overall challenges in incorporating recycled content in medical packaging today.

Quality Compliance

Product safety is of utmost priority within the healthcare packaging industry. ISO 13485 certification is an important quality requirement for medical devices and requires a clear record of the original source of all materials used in medical device packaging as well as the processes used. ISO 13485:2016 and U.S. 21 CFR 820.65 require a device history record (DHR) that traces the materials used to create the medical device and packaging back to their raw material sources. When considering the inclusion of recycled content in medical device and packaging design, raw material traceability presents challenges, especially when considering PCR materials. For PIR, this traceability requirement is much more achievable because the supplier has the opportunity to keep a record of where the materials originated.

Risk of Variation in Material

Recycled content may pose risks related to color variations, mechanical performance, and processability. Consequently, recyclers continually strive to improve their processes and consistency with the aim of enhancing overall material quality. The quality of recycled materials may vary depending on the supplier and the original material source. Material purity is critical in medical device and packaging production in order to avoid material performance risks. Use of the ISO 14971 standard, Application of Risk Management to Medical Devices, may benefit medical device manufacturers as they strive to ensure that all areas of risk are addressed and properly managed.

Supply Constraints
Recycled materials are in high demand across the packaging industry. Consequently, suppliers may be faced with challenges when trying to procure a consistent supply. As the use of recycled materials is considered, it is important to discuss the potential for supply constraints with your supplier and to have multiple sources of recycled materials qualified when possible. As new sortation and recycling technologies continue to develop, the supply of recycled materials will become more reliable and consistent.

Despite these challenges, there are still many opportunities for recycled content to be used in healthcare packaging today.

ONGOING EFFORTS

As recycling technology evolves and recommendations for recycled material use change, HPRC will continue to revise and update this guidance to reflect the most accurate and up-to-date information.

HPRC is actively engaged with Circular Economy and New Plastics Economy concepts, working to create actionable tools and guidelines to enable healthcare plastics to be a leader in circular economy best practices. We remain committed to our mission to collaborate across the value chain to inspire and enable the healthcare community to implement viable, safe, and cost-effective recycling solutions for plastic products and packaging used in the delivery of healthcare. Explore more HPRC resources and learn about our solutions development at https://www.hprc.org/resources/.

With any questions, comments, or feedback on this design guidance, please contact us through our website.

APPENDIX / GLOSSARY

Advanced Recycling	Also known as chemical or molecular recycling, refers to various technologies which break down plastics through purification, decomposition/depolymerization, or thermal conversion in order to create purified polymers, monomers and intermediates, or basic hydrocarbons, respectively, that can then be used to make new plastic products.
Association of Plastics Recyclers (APR)	International trade association representing the plastics recycling industry.
Circular Economy	A model of production and consumption that reuses, refurbishes, and recycles existing materials and products as long as possible.
Circular Economy for Flexible Packaging (CEFLEX) Initiative	Collaboration of over 180 European companies, associations, and organizations representing the value chain of flexible packaging, working to make all flexible packaging in Europe circular by 2025.
Contaminant	Materials that degrade the purity of the recyclable content or hinder the recycling process. Contaminants are commonly introduced when materials are sorted into the wrong recycling stream. In a hospital setting, sources of contamination may include biological materials (biohazardous contamination).
Direct Printing	Printing which is applied directly to the substrate during the package filling process. This approach may reduce the use of labeling on the package.
Flexible Blister / Tray	Similar to a flexible pouch / bag but requiring that one web component be composed of a thermoformable material (e.g., plastic film). The corresponding web component may be made of plastic film as well or non-woven HDPE, paper, etc.
Flexible Pouch / Bag	A type of flexible packaging that can be composed of multiple material combinations, including film-to-film, film-to-porous material (e.g., non-woven HDPE, paper), film-to-metal foil, etc.
International Organization for Standardization (ISO)	International standard development organization

International Sustainability and Carbon Certification (ISCC)	Certification system for traceable and deforestation free supply chains
Lidding	Top web material that is typically die cut to size prior to being sealed to a rigid / semi-rigid tray. Typical material options may include non-woven HDPE and paper.
Life Cycle Assessment (LCA)	Methodology for assessing environmental impacts associated with all the stages of the life cycle of a commercial product, process, or service.
Mechanical Recycling	Treatment of plastics through processes such as grinding, washing, and separating to create recycled resins by re-granulating and compounding that can be used to make new plastic products.
Post-Consumer Recycled (PCR) Content	New resin material created from the recycled waste materials discarded by consumers or industry.
Post-Industrial Recycled (PIR) Content	Scrap material waste generated during mass production that is reintegrated into the manufacturing process to manufacture new products. PIR content circulates within a closed-loop system and is reintroduced into the manufacturing process before departing the facility as a waste product.
Recycling	The process of converting waste into usable material.
Recyclable	Per the Federal Trade Commission's Green Guides, the following criteria must be met to claim a product is recyclable: • Collection – 60% of Americans must have access to collection systems for the item. • Sorting – It must be able to be sorted with like items and materials. • Reprocessing – It can be converted into a reusable material in an economical manner. • End Markets – Robust end markets for the recycled material must be available.
RecyClass	Non-profit, cross-industry initiative focused on advancing plastic packaging recyclability and ensuring traceability and transparency of recycled plastic content in Europe.

Recycled Content	Material derived from recycling a product.
Resin Identification Codes (RICs)	Numerical coding system for the labeling of plastic products that contain numbers to identify the resin type that composes the product.
Rigid / Semi-Rigid Blister / Tray	Rigid or semi-rigid trays are a type of self-supporting package that is typically created from a thermoformed plastic. The tray, which encapsulates the device(s), is then paired with a suitable lidding material to form the complete sterile packaging.
Soy-Based Inks	Inks that are derived from soybeans. Soy-based inks are environmentally friendly, provide precise colors, and make it easier to recycle the substrates they are used with.
Substrate	A layer that lies under the surface of another layer or coating.
Sustainability	Meeting the needs of the present without compromising the ability of future generations to meet their own needs.
Sustainable Packaging Coalition (SPC)	Membership-based collaborative focused on making packaging more sustainable.
User-Friendly Labeling	A system of symbols or markings that inform the consumer how to properly dispose of the product materials.
Water-Based Inks	Inks that use water as the main solvent for carrying pigment.

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ABOUT HPRC

HPRC is a private technical coalition of industry peers across healthcare, recycling, and waste management industries seeking to improve the recyclability of plastic products within healthcare. Made up of brand-leading and globally recognized members, HPRC explores ways to enhance the economics, efficiency, and ultimately the quality and quantity of healthcare plastics collected for recycling. HPRC is active across the United States and Europe working with key stakeholders, identifying opportunities for collaboration, and participating in industry events and forums.

For more information, visit *www.hprc.org* and follow HPRC on LinkedIn.

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