REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by Padmini Ranasinghe, MD, MPH, Chair:

1. DRUG SHORTAGES: 2025 UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue. CSAPH has issued 15 reports on drug shortages, with the most recent presented at the 2024 Interim Meeting. The remainder of this report will provide an update on drug shortages since the 2024 report was developed.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2022 to June 2025, using the text terms "drug shortages." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine, U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), and Duke Margolis Institute for Health Policy, and contemporary media reporting.

DISCUSSION

Drug shortages remain an ongoing and complex public health concern in the United States with new and emerging challenges to the supply chain. The FDA defines a drug shortage as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[1] Drug shortages may occur for a variety of reasons, including disruptions to the supply chain, a limited number of manufacturers, small profit margins, regulatory burdens, natural disasters, or surges in demand.[2–5] The number of new drug shortages was reduced markedly, and total drug shortages were reduced modestly, in 2024 from all-time highs in 2023.[6] While this reduction in drug shortages is welcome news after a decade of growth, overall drug prices increased during that same period which may have future implications on drug shortages and their resolution based on changes in their financial margins.

The two primary data sources for information on drug shortages in the United States are the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service (see Box 1 for links to these resources). The FDA collects drug shortage information for their database directly from the drug manufacturers via their voluntary submission of information and defines a drug shortage to be when a manufacturer cannot meet current market demand as self-identified. Alternatively, the ASHP drug shortages database is based on reports from health care practitioners or patients/caregivers, which is then verified with manufacturers by the University of Utah Drug

Information Service to confirm the shortage status for inclusion in their list. Since the FDA database has a more limited definition of a drug shortage and requires self-reporting from manufacturers, their drug shortage numbers and statistics tend to be smaller and vary somewhat from those reported in the ASHP drug shortages database statistics.

According to ASHP statistics (Appendix 1), trends in all active drug shortages have stabilized quarter by quarter in 2024 with a decrease from 2023 (Figure 1).[7] Overall, new drug shortages (130 per ASHP and 98 per USP/FDA) decreased in 2024 compared to new drug shortages (156 per ASHP and 125 per USP/FDA) in 2023 (Figure 2 and Figure 3).[6,8] The number of new drug shortages remained higher among injectable products compared to all other dosage forms, such as oral or topical products (Figure 3 and Figure 4). The majority of new drug shortages still involve injectable products; this proportion has remained relatively stable, despite continued supply chain challenges this past

year with IV fluid products. The most common drug classes with active shortages (as of June 2025) include: central nervous system therapies (n=48), antimicrobials (n=36), fluids/electrolytes (n=26), hormones (n=25), and chemotherapies (n=23), consistent with trends across the last five years (Figure 5 and Figure 6).[7,8]

Despite fewer drug shortages in 2024, the complexities of the supply chain remain, causing each shortage to last longer, increasing the persistence of drug shortages in the market impacting patient care and practice. The average duration of a drug shortage in 2024 was 1,585 days (4.2 years) compared to 706 days (two years) in 2019 (Figure 7).[6,9] In December of 2024, there were approximately 25 drugs in shortage for longer than five years.[6,9] From FDA Center for Drug Evaluation and Research (CDER) data, 91 percent of the drug shortages in 2024 had persisted for over one year. All five drugs that have been in a shortage for greater than 10 years are injectable medications that are deemed essential medicines by either the FDA or the WHO, highlighting the challenge and impact these drug shortages can have.[6] The eleventh annual report on drug shortages from the FDA to Congress was published in early 2024 and summarized the work of the FDA in calendar year 2023 related to drug shortages.[10] The annual report for calendar year 2024 was not available at the time of this report.

The lack of clarity and shift in causes of drug shortages year-to-year makes targeted improvements challenging. The most common reason for drug shortages in 2024 was unknown or not reported (55 percent) [Figure 8], which is similar to 2023. However, hurricane damage to manufacturing was a unique reason for drug shortages in 2024 compared to 2023. Manufacturing, business decisions by pharmaceutical companies, and supply/demand remain the most common reasons noted, with raw material issues comprising a smaller component of drug shortages.[7,8]

Hurricane Helene and IV Fluid Shortages

In September 2024, a Baxter manufacturing plant in North Cove, North Carolina, was subject to devastating flooding from Hurricane Helene, closing the plant.[11,12] This manufacturing facility was the largest manufacturing facility of IV fluids and peritoneal dialysis (PD) solutions in the U.S. as well as being Baxter's largest manufacturing facility worldwide with over 1 million IV solutions produced daily onsite.[12] Baxter moved into an allocation model for distribution and also quickly began recovery measures for restoring the manufacturing plant, yet it took nearly eight weeks after the storm for the first products produced post-hurricane to be released.[12] Without this manufacturing facility that produced approximately 60 percent of IV fluids pre-hurricane, significant IV fluid shortages and PD solution shortages were imminent. The FDA responded by working with Baxter to extend "beyond use" dates of some IV fluid products from one year to two years in order to lessen the impact of the shortages.[13] The U.S. Department of Health and Human Services also responded with communications on IV fluid conservation practices for hospitals to help mitigate challenges from the IV fluid shortages.[14,15] Despite conservation measures and increased access with extended beyond use dates, the impacts of the IV fluid and PD solution shortages seriously affected hospitals, physicians and patients resulting in cancelled surgeries and delayed treatments.[16] Baxter was able to resume pre-hurricane production levels and removed all allocation procedures on their IV fluid and PD solution products in February of 2025, but many IV injectable shortages remain.[7,12] This was unfortunately not the first instance of extreme weather causing a drug shortage, but the regulatory flexibility with extended beyond use dates and allocation models supported minimization of challenges.[15] Your Council notes that extreme weather events, whose location may be difficult to predict, may become a more frequent cause of drug shortages as climate change accelerates.

The Hidden Cost of Drug Supply Chain Disruptions

Vizient, a health care consulting firm, conducted a survey in summer 2024 of their member organizations, typically hospital or health-system pharmacy departments, to review the impact of drug shortages. The survey results highlighted the increased financial and workforce demand caused by drug shortages, including increases in time needed by staff to manage drug shortages and the associated cost on pharmacy budgets.[17] Beyond financial challenges, communication gaps were additionally identified, limiting the ability for proactive drug shortage stewardship efforts.[17,18] Finally, it was noted that pediatric facilities were impacted at higher rates than adult facilities due to the intricacies and risk of pediatric drug formulations.[17] This survey highlights the disproportionate and growing impact of drug shortages for patient care, the health care workforce, and on costs. A link to their survey results has been included in Box 1 of this report.

U.S. Government Accountability Office Study

As a provision of the Cares Act of 2020, the U.S. Government Accountability Office (GAO) was tasked with describing the trends in drug shortages and steps for the FDA to improve drug shortage prevention and response.[19] This report mirrored the detailed yearly trends reported by the ASHP and US Pharmacopeia (USP), highlighting the slight reduction in the number of drug shortages, but the stark increase in the duration to resolve a drug shortage compared to pre-pandemic statistics (Figure 10).[6,7,19] The GAO described key challenges that cause drug shortages including the lack of incentives for producing low profit drugs, limited ability to recognize manufacturers with high-level quality management systems to share best practices, and the complex and fragmented supply chain; all challenges addressed in previous CSAPH Drug Shortages reports.[19] Recognizing drug shortages are a complex issue impacting the U.S., the GAO recommended a collaborative, interagency governmental approach moving forward to reduce negative impacts. Key collaboration practices include: 1. Define common outcomes, 2. Ensure accountability, 3. Bridge organizational cultures, 4. Identify and sustain leadership, 5. Clarify roles and responsibilities, 6. Include relevant participants, 7. Leverage resources and information, and 8. Develop and update written guidance and agreements.[19]

AN EVOLVING POLITICAL LANDSCAPE: POTENTIAL CHALLENGES FOR DRUG SHORTAGES

Drugs shortages are complex, multi-factorial problems, with small changes having large, cascading effects down the supply chain. In this year's survey of the drug shortages landscape, the evolving political landscape is challenging with uncertainty around both specific actions and timelines. This report highlights the key policy challenges and the potential impacts of pharmaceutical tariffs, and reduction in the FDA workforce on drug shortages in the U.S.

Challenge: Pharmaceutical Tariffs

As a mechanism for reducing drug shortages, there has been interest in onshoring or increasing domestic pharmaceutical manufacturing based on a common belief and myth that the majority of manufacturing is occurring internationally, particularly in China and India.[20] Data from USP Medicine Supply Map[21] show that while a majority of oral solid products (60 percent) are produced in India, the largest share of injectable products (45 percent) are manufactured in the U.S. (Figure 9).[9] Further, the majority of oral solid products (66 percent) and injectables (58 percent) that were in shortage at the end of 2024 were manufactured in the U.S. (Figure 9). It is unclear whether shifting pharmaceutical manufacturing to the U.S. or nearby countries (onshoring or nearshoring) would have any impact on drug shortages in the U.S.

The Department of Commerce launched an investigation on April 1, 2025, under Section 232 of the Trade Expansion Act (19 U.S.C. 1862) to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products. This includes both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items.[22,23] This investigation calls for federal tariffs to be placed on a wide range of pharmaceutical products for potential national security concerns.[23] Reporting initially indicated that the tariffs on pharmaceutical products would be enacted within a month or two of the April investigation and could be as high as 200 percent. However, the implementation date and tariff level have shifted multiple times and at the time of this report, have yet to be implemented.[23,24] However, if implemented, companies would reportedly be provided a grace period of unknown duration.[25]

In response to the potential of tariffs on pharmaceutical products, pharmaceutical organizations, international allies, and stakeholders have responded swiftly. Pharmaceutical Research and Manufacturers of America (PhRMA) submitted formal comments to the U.S. Department of Commerce in response to the investigation indicating the imposition of tariffs on pharmaceutical products would be dire.[26] Among other reasons, PhRMA and other groups noted tariffs would hinder innovation and leadership stature in the pharmaceutical market.[26–28] The European Union was also quick to respond to the investigation, noting their longstanding trade partnerships and the interconnectivity of the markets, where U.S. tariffs could cause significant supply chain disruptions.[18,28] The generic drug supply may be at even further risk with the imposition of tariffs considering much of the generic oral agents are manufactured abroad and the financial margins on generic drugs are so small it would disincentivize continued production or pass along the cost to consumers.[6] Additional impacts are not completely known, however reduced innovation from increased costs, retaliatory trade measures from other countries, challenges accessing active pharmaceutical

ingredients, decreased access to medications for patients, and increased out of pocket costs are all likely consequences.[29,30]

Pharmaceutical companies have responded to the threat of potential tariffs. In February, Eli Lilly announced plans to bolster U.S. manufacturing of their products by building four new manufacturing facilities.[31] AbbVie followed by announcing a $10 billion investment in U.S. manufacturing over 10 years, while AstraZeneca announced a $50 billion investment plan, with U.S. manufacturing facilities planned and research and development infrastructure, among other pharmaceutical companies announcing investments.[25,32] Despite the threat of tariffs on pharmaceutical products spurring announcements of investments in U.S. manufacturing, these investments are unlikely to have positive near term impact on drug supply due to the complexities of building a pharmaceutical manufacturing site and the lengthy regulatory pathway for approval of a site once it has been constructed.

Challenge: Changing FDA Workforce

On February 11, 2025 President Trump signed an executive order entitled, "*Implementing The President's "Department of Government Efficiency" Workforce Optimization Initiative (Workforce Optimization)*" which sought to 'eliminate waste, bloat, and insularity' in the federal government workforce.[33] Under the direction of the Office of Management and Budget and the Office of Personnel Management, federal agencies were instructed to 'seek reductions in components and positions that are non-critical,' amongst other areas for an overall reduction in force.[34]

The FDA saw approximately 3500 layoffs in March 2025, or nearly 20 percent of their workforce due to this action.[35,36] A U.S. GAO report highlighted the fragility and importance of the FDA inspectors workforce since the COVID-19 pandemic caused a backlog of inspections as well as inspectors leaving their posts due to work-life balance concerns.[37] In light of this report, the Trump Administration vowed to not reduce the FDA inspector workforce. However, initial reports highlight significant cuts to the administrative staff of the FDA inspectors and freezing credit limits on work-issued credit cards, hamstringing their ability to make timely inspections, particularly in international locations.[38] FDA is also a critical contributor to onboarding new manufacturing facilities (like Lilly and AbbVie have promised) as they must provide regulatory approval for a site to begin manufacturing. Bottlenecks from reduced FDA staffing will slow down the pace of onshoring.

FDA's Center for Drug Evaluation and Research's (CDER) and the Center for Biologics Evaluation and Research's (CBER) were not immune to staffing cuts. In fiscal year 2025, CDER and CBER lost 353 and 34 employees, respectively. Collectively, this reduction in the workforce produces significant risks for drug shortages. FDA inspectors are critical components to bringing transparency to the supply chain and identifying quality concerns proactively.[6,38] CDER and CBER have important roles in communicating drug shortages from manufacturers to health professionals and the public.[39] Bioequivalence studies used to add additional manufacturing sites for a product require review by CDER/CBER, so products could go into shortage awaiting review. Usually, these sites also are subject to pre-approval inspections, so inspection delays could additionally delay this process. Further, the Senate Appropriations Committee and other pharmaceutical and biotechnology firms highlight the FDA reduction in force is hindering the drug review process that may have implications in innovation in the market, a necessary component of flexibility during times of drug shortages.[40,41]

Recently, the FDA has announced interest in utilizing augmented/artificial intelligence (AI) to support various functions, such as drug reviews and inspections, previously completed by the human workforce.[42] While the use of AI by the FDA is posited for efficiency in their work, the risk of hallucinations, which is where AI models provide false or misleading information, is always there. AI may mitigate or offset some of the backlog of work related to decreased staff, but in bulk, there will be errors that may cause harm and should always fallback to humans to ensure safe products.[43]

ONGOING AMA ACTIVITIES

AMA staff continue to remain engaged in drug shortage activities. Staff are involved in the Drug Shortages Task Force, a multi-stakeholder, national task force effort to remain current on policies, drug shortage and supply chain issues, and to develop group recommendations on the topics, many of which are already contained within AMA policy. The effort includes over 20 organizations, including our AMA, ASHP, American Hospital Association, United States Pharmacopeia, American Society of Anesthesiologists, and the American Society of Clinical Oncology, among others

to raise awareness of the severe harms of shortages and the causes behind them, provide insights to inform data-driven solutions, and advocate for reforms in a collaborative and productive manner.[44]

Additional advocacy efforts have been taken since the 2024 drug shortages report, including communication with the Federal Trade Commission regarding drug shortages,[45] correspondence with the Senate Finance Committee on a drug shortage discussion draft,[46] real-time collaborative efforts to partner with HHS in the aftermath of Hurricane Helene and the subsequent IV fluid shortages,[47] and communication with the Centers for Medicare & Medicaid Services on the potential for drug shortages with implementation of their $2 Drug List Model.[48]

In light of Hurricane Helene's destruction of manufacturing plants in North Carolina that caused ongoing, significant IV fluid shortages, our AMA has worked to provide better resources for our members regarding drug shortages beyond this annual report. The AMA Drug Shortages Resource Webpage is a public site with information on ongoing shortages, links to resource pages with clinical information, and highlights additional efforts at our AMA on drug shortages (Box 1).

At the 2025 AMA Annual Meeting, two resolutions relevant to drug shortages were adopted by the HOD. Resolution 210-A-25 was adopted as amended. The resulting policy, D-110.981, "Impact of Tariffs on Healthcare Access and Costs," calls on our AMA to "actively monitor and assess the impact of current and proposed tariffs on healthcare costs and patient access to medical services" and "support legislative efforts aimed at mitigating the negative effects of tariffs on the healthcare system, ensuring that patient care, medical supplies, and pharmaceuticals remain accessible and affordable."

Resolution 522-A-25, resulting in policy D-100.959, "Access to Important and Essential Drugs," asks that our AMA urge Congress to pass comprehensive legislation to mitigate existing drug shortages and prevent future shortages of lifesaving and life-prolonging drugs. The policy also states that a comprehensive approach would include, but not be limited to the following:

- Address economic factors that drive generic manufacturers out of the market and consider stabilizing the market with long-term contracts and guaranteed prices.
- Reward reliable U.S. manufacturing of critical and supportive medications through prices that support continued quality production and investment in continuous manufacturing or other advanced manufacturing for critical drugs and active pharmaceutical ingredients (APIs), which could include onshoring or nearshoring as components of a solution.
- Recognize potential shortages earlier by increasing the FDA's visibility into the supply chain so the agency can predict and respond to potential shortages earlier.
- Relay information about potential shortages to health systems and providers to help them prepare for and mitigate possible supply challenges.

CONCLUSION

Drug shortages continue to be a persistent problem resulting in risks to patient health and safety. In this annual update on drug shortages, trends highlight the reduction in overall drug shortages, but the increased time to resolve a shortage. New risks may be imminent for drug shortages secondary to changes in the political landscape and policy agenda, particularly with pharmaceutical tariffs and changes in the federal workforce. Extensive AMA policy has supported stakeholder engagement in 2024 and early 2025 and continues to allow the AMA to advocate for mechanisms to support pharmaceutical access by reducing drug shortages proactively and mitigating impact when they occur.

Fiscal Note: Minimal

CITED POLICIES

National Drug Shortages H-100.956

1. Our American Medical Association considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations and pharmacy benefit managers on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing Organization (GPO), pharmacy benefit managers, and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers, and supports efforts by the Federal Trade Commission to oversee and regulate such forces.
7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market or caused to stop production due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers and distributors to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, any unpredicted changes in product demand, and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.
13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of global reporting requirements for indicators of drug shortages.
14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing, and supports the use of incentives such as prioritized regulatory review, reduction of user fees, and direct grant opportunities for manufacturers seeking to invest in manufacturing processes.
15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.
16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.

17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.
19. Our AMA urges the Drug Enforcement Agency and other federal agencies to regularly communicate and consult with the FDA regarding regulatory actions which may impact the manufacturing, sourcing, and distribution of drugs and their ingredients.
20. Our AMA supports innovative approaches for diversifying the generic drug manufacturing base to move away from single-site manufacturing, increasing redundancy, and maintaining a minimum number of manufacturers for essential medicines.
21. Our AMA supports the public availability of FDA facility inspection reports to allow purchasers to better assess supply chain risk.
22. Our AMA opposes the practice of preferring drugs experiencing a shortage on approved pharmacy formularies when other, similarly effective drugs are available in adequate supply but otherwise excluded from formularies or coverage plans.
23. Our AMA shall continue to monitor proposed methodologies for and the implications of a buffer supply model for the purposes of reducing drug shortages and will report its findings as necessary.
24. Our AMA opposes increasing drug prices or waiving fee exemptions in a manner that incentivizes a drug manufacturer to have its drug be declared in shortage.
25. Our AMA opposes the use of punitive fees on physician practices that do not maintain buffer supplies of drugs.
26. Our AMA encourages the FDA, the FTC, or other relevant oversight entities, to examine the practice of compounding pharmacies and the entities that utilize them advertising drugs actively in shortage, particularly when targeted to new patients.

Drug Shortages: 2024 Update D-100.961

1. Our American Medical Association opposes laws, regulations, or business practices which create artificial scarcity of drugs, such as limitations on pharmacy procurement or restrictions on which pharmacies a patient can use, which prevent the filling of an otherwise valid prescription from their physician.
2. Our AMA advocates for pharmacies and distributors subject to the national opioid litigation settlement to make public the specific metrics, formulas, data sources, algorithms, thresholds and other policies and analyses that are used to delay or deny orders to pharmacies, restrict physicians' prescribing privileges and other actions that impede patients' access to medication.
3. Our AMA advocates for pharmacies and distributors to provide physicians with all due process rights and opportunities to contest any decision to restrict a physician's prescribing privileges based on a pharmacy or distributor metric, formula, algorithm or other policy before such restriction is put into effect.
4. Our AMA urges the Centers for Medicare & Medicaid Services to implement policies to temporarily halt financial and other penalties for affected quality metrics during periods of documented medication and IV fluid shortages as well as in other emergencies in order to prevent physicians and hospitals from being penalized for circumstances beyond their control.

Drug Manufacturing Safety H-100.945

1. Our American Medical Association supports efforts to ensure that the U.S. Food and Drug Administration (FDA) resumes inspections of all drug manufacturing facilities on a frequent and rigorous basis, as done in the past.
2. Our AMA will call for the FDA to:
    a. assure the safety of the manufacture of drugs, drug ingredients and precursors.
    b. work proactively with industry to prevent or minimize drug shortages.
    c. work with the industry to oversee the adequacy of product in the pipeline.

Non-Profit or Public Manufacturing of Drugs to Address Generic Drug Shortages H-100.942

1. Our American Medical Association supports activities which may lead to the stabilization of the generic drug market by non-profit or public entities. Stabilization of the market may include, but is not limited to, activities such as government-operated manufacturing of generic drugs, the manufacturing or purchasing of the required active pharmaceutical ingredients, or fill-finish. Non-profit or public entities should prioritize instances of generic drugs that are actively, at-risk of, or have a history of being, in shortage, and for which these activities would decrease reliance on a small number of manufacturers outside the United States.

2. Our AMA encourages government entities to stabilize the generic drug supply market by piloting innovative incentive models for private companies which do not create artificial shortages for the purposes of obtaining said incentives.

Group Purchasing Organizations and Pharmacy Benefit Manager Safe Harbor D-100.967
Our AMA will: (1) renew efforts urging the federal government to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures subject to the Group Purchasing Organization and PBMs anti-kickback safe harbor, including the potential impact on drug pricing and drug shortages; (2) support efforts to update and modernize the fraud and abuse laws and regulations to address changes in the health care delivery and payment systems including the potential impact on drug pricing and drug shortages; and (3) via a letter, immediately ask the Secretary of HHS and other appropriate stakeholders to request the HHS OIG to examine the supply chain of pharmaceuticals, pharmacy benefit managers, Safe Harbor laws and regulations, and expeditiously make recommendations to make prescription drugs more accessible and affordable to patients with an emphasis on examining the governing contracts for drugs in short supply and/or that are exceedingly expensive to ensure compliance with all the safe harbor provisions.

Pharmaceutical Costs H-110.987
1. Our American Medical Association encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports:
    a. drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase;
    b. legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and
    c. the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation

Box 1. Resources available to assist in mitigation of drug shortages.

1. FDA Drug Shortages Page (includes current shortages list, extended use dates, mobile app, and additional information)
2. ASHP Resource Center
3. ASHP list of current shortages
4. AMA Drug Shortages Resource Webpage
5. Vizient member survey on current drug shortages

Appendix 1

Figure 1. National Drug Shortages: Active Shortages by Quarter: 10 Year Trend[7,8]

Figure 2. New Drug Shortages by Year: January 2001 to June 30, 2025 (ASHP)[7,8]

Figure 3. New Drug Shortages by Year: 2014 to 2024 (USP/CDER)[6]

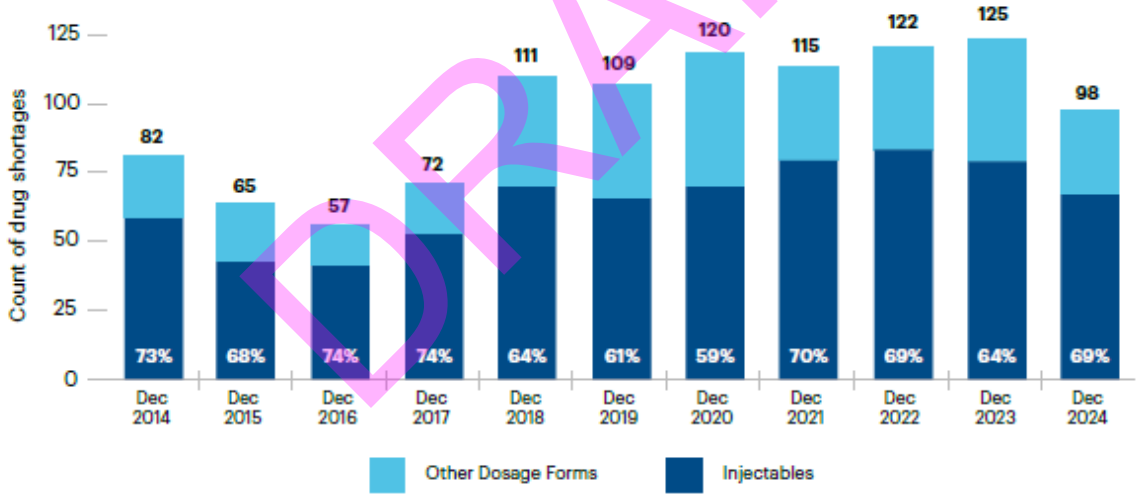


Figure 4. National New Drug Shortages by Year: January 2001 to June 2025, % Injectable[7,8]

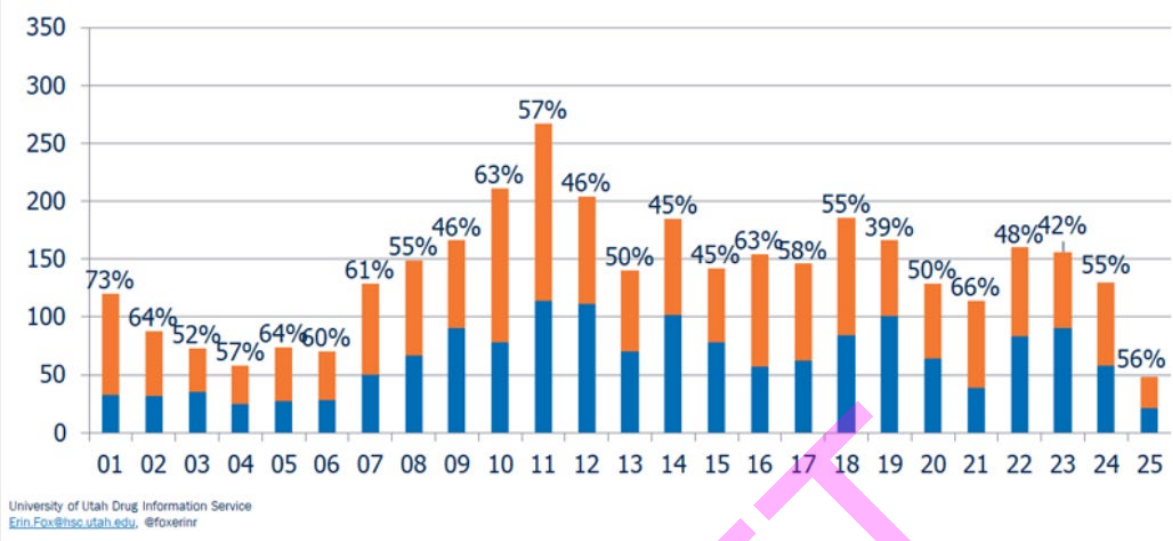


Figure 5. National Active Drug Shortages: Top 5 Drug Classes[7,8]

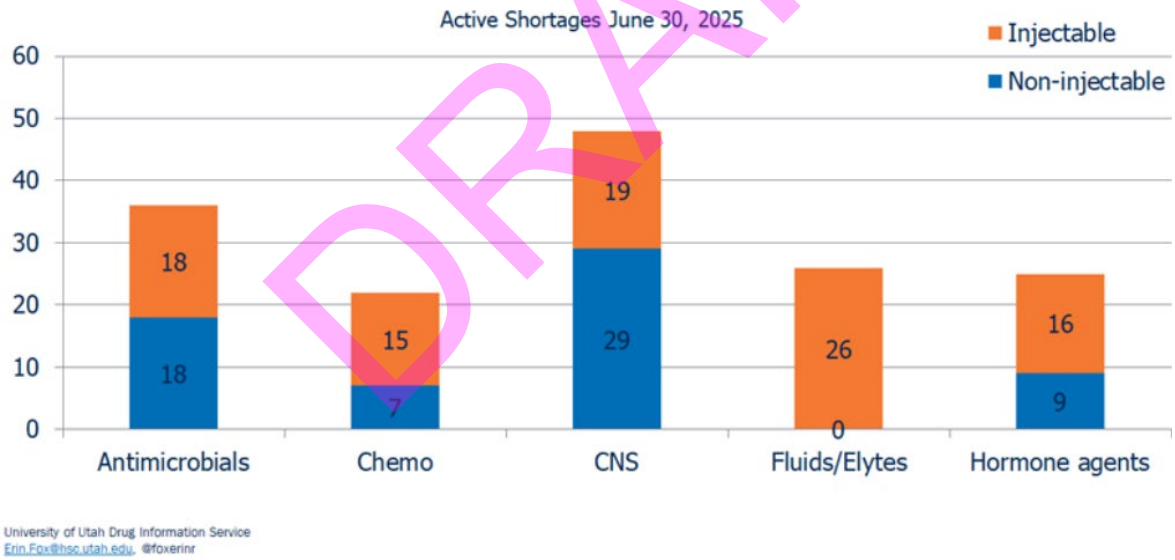


Figure 6. Common Drug Classes in Short Supply: 5 Year Trend[7,8]

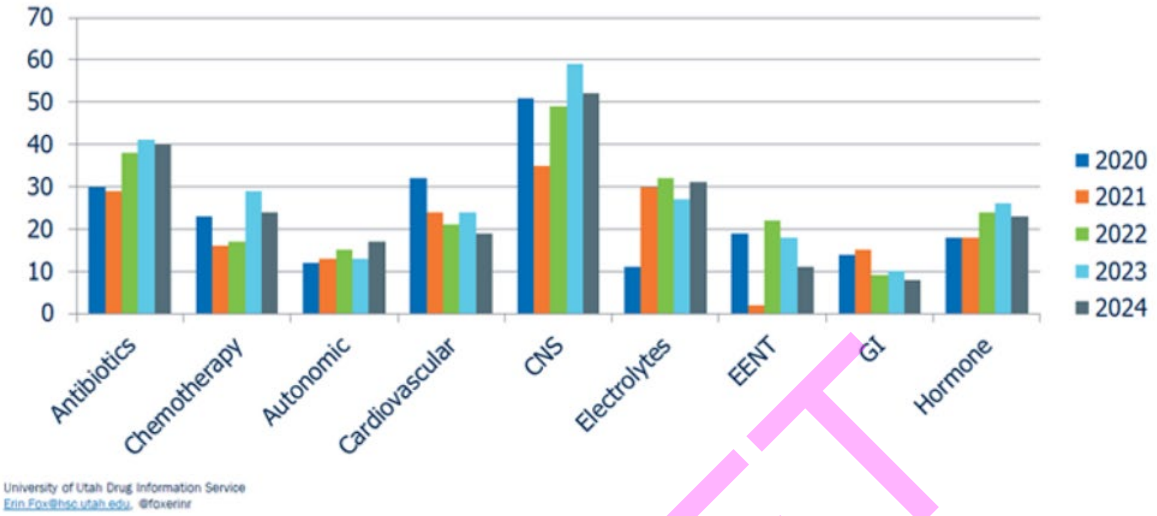


Figure 7. Average Duration of Drug Shortages by Year (USP/CDER)[6,9]

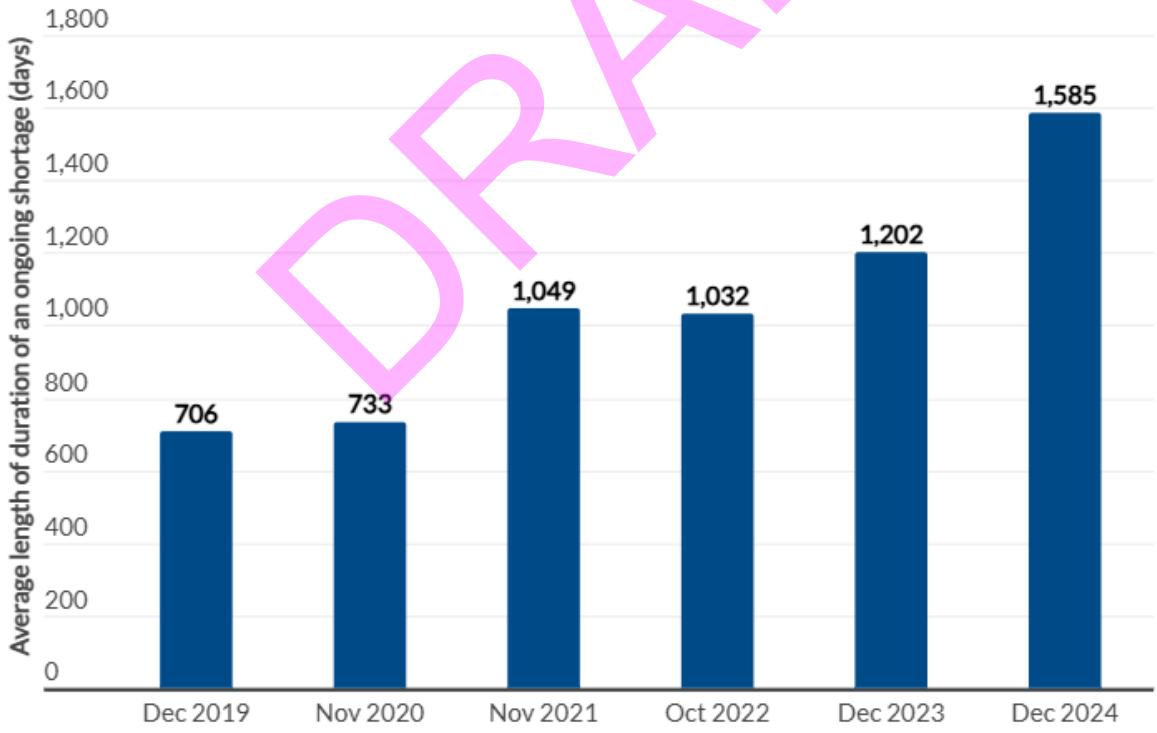


Figure 8. Reasons for Drug Shortages as Reported by Manufacturers During UUDIS Investigation 2023 and 2024[7,8]

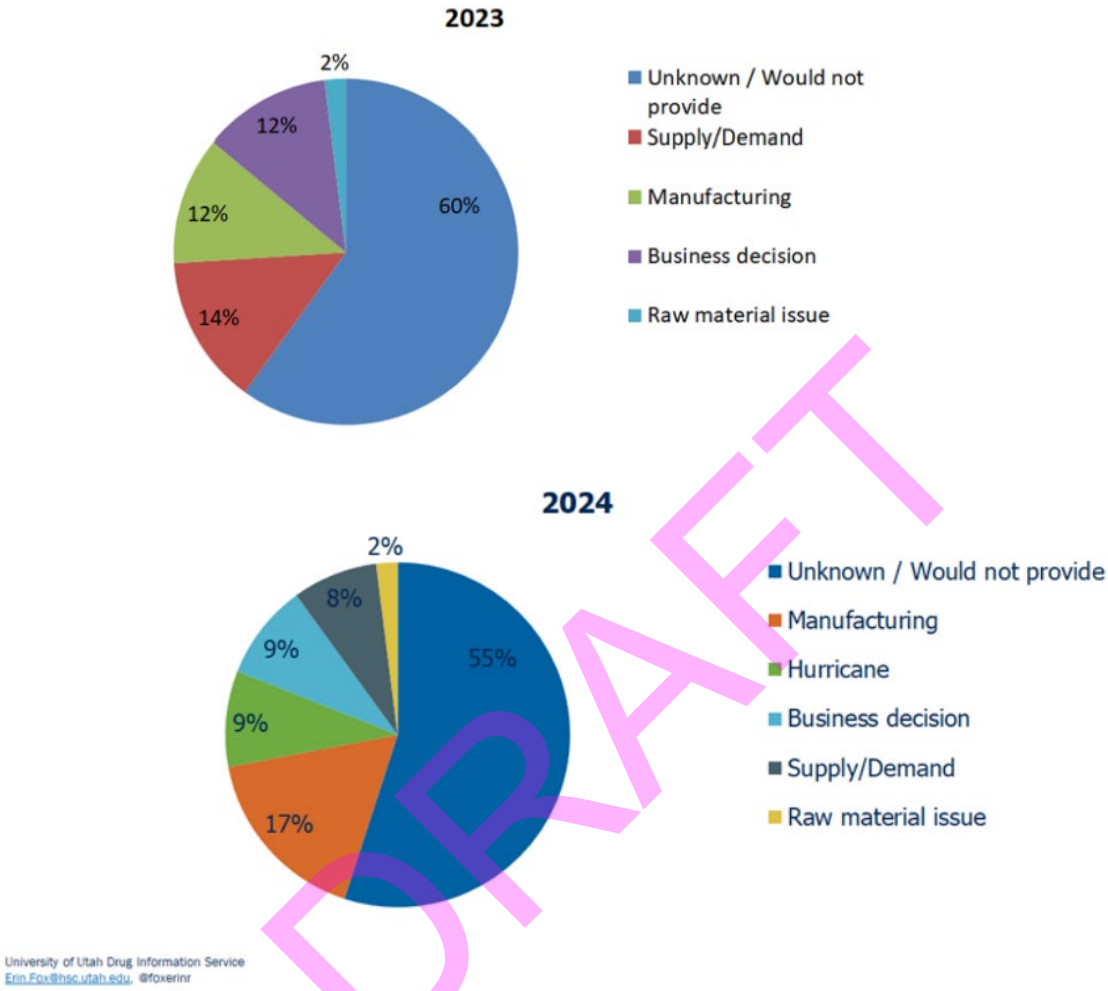
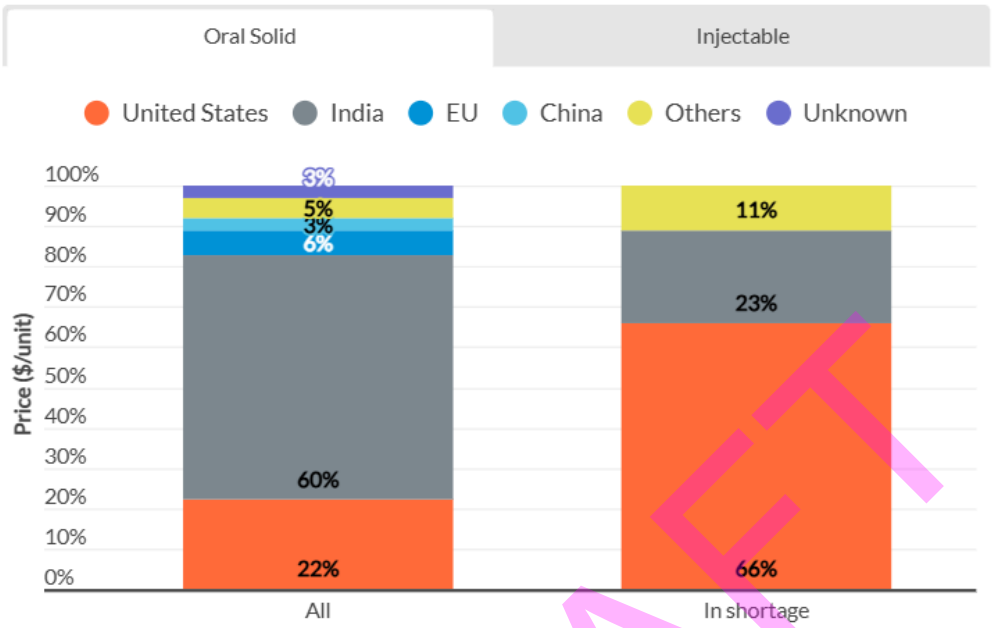


Figure 9. Geographic Distribution of Manufacturing for Oral Solid (A) and Injectable Products (B) for All and In Shortage

A: Oral Solid Products



B: Injectable Products

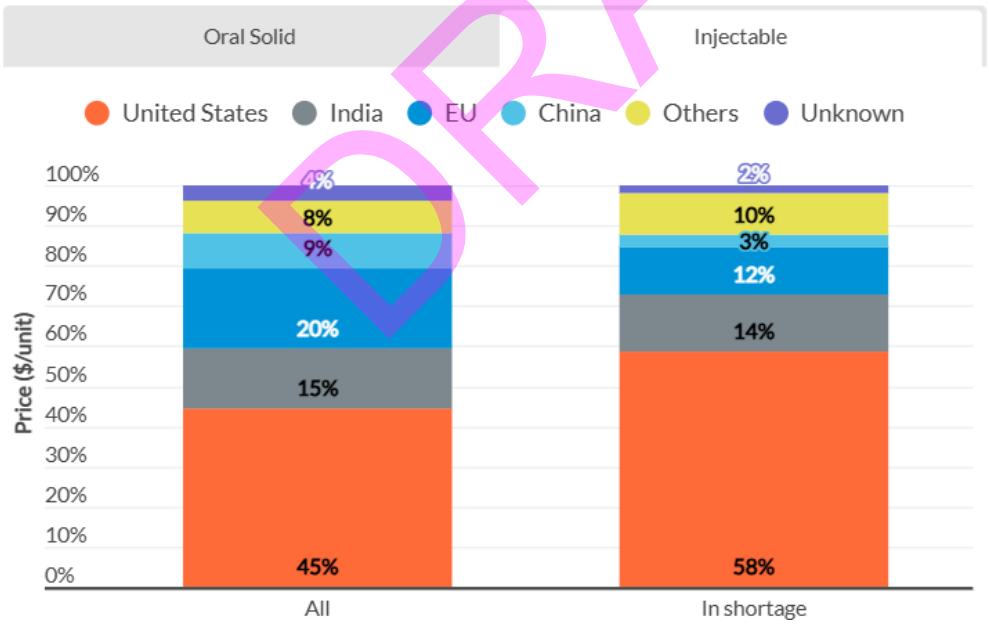
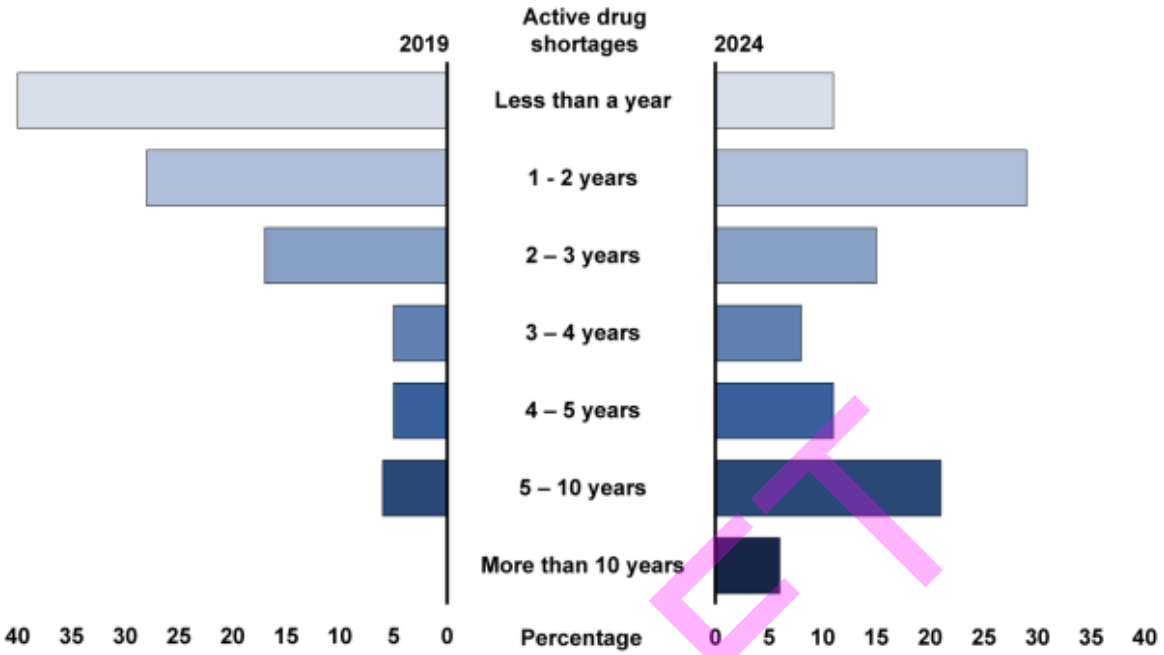


Figure 10. Drug Shortage Duration from December 2019 versus July 2024[19]



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2. REGULATION OF IONIZING RADIATION EXPOSURE FOR HEALTH CARE PROFESSIONALS

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy H-455.975

AMA Policy H-455.975, "Regulation of Ionizing Radiation Exposure for Health Care Workers," was adopted at the 2024 Interim Meeting of the AMA House of Delegates (HOD). The policy asks the following:

1. Our American Medical Association encourages public and private healthcare institutions to ensure comprehensive coverage of different body types by providing readily available PPE that reduces exposure to as low as reasonably achievable for employees of all genders and pregnancy statuses.
2. Our AMA will work with the appropriate and interested parties to study how best to accomplish comprehensive protection from ionizing radiation for employees, taking into account variation in body types, pregnancy status, specifics of procedures being performed, as well as how exposure can be limited beyond PPE (personal protected equipment), with report back at I-25.

Furthermore, resolution 505-A-25, "Mandating Properly Fitting Lead Aprons in Hospitals," was referred. That resolution asked that our American Medical Association collaborate with relevant stakeholders to ensure:

1. Adequate stocking of diverse lead apron sizes for all radiation-exposed personnel and medical trainees, and
2. Consistent implementation of evidence-based radiation safety principles to keep exposure as low as reasonably achievable in accordance with specialty society guidelines, in order to promote optimal protection practices.

Given that both resolutions relate to the same topic, they will be addressed together in this report.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases using the search terms: "occupational exposure" and "ionizing radiation"; "health care" and "ionizing radiation"; "radiation safety" and "health care". Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal agencies and applicable professional organizations were also reviewed for relevant information.

DISCUSSION

Ionizing radiation is high-energy radiation that has enough energy to remove an electron (negative particle) from an atom or molecule. It can cause chemical changes in cells and damage DNA, thereby increasing the risk of developing certain health conditions. In health care settings, ionizing radiation can come from nuclear medicine and medical imaging equipment, such as x-ray, fluoroscopy, CT scan, or PET scan machines. Diagnostic imaging in health care has been growing rapidly in the U.S. and around the world. Approximately 93 million CT scans are done on 62 million patients in the U.S. annually.[1] When considering X-rays, mammograms, PET scans, and fluoroscopic procedures, patients' exposures to medical radiation is not insignificant. At the current rate of CT scans usage, five percent of future cancers will be due to this imaging modality alone.[1]

Most research and recommendations on radiation safety in health care focus on patients, aiming to minimize their exposure by reducing both the amount of radiation per test and the total number of tests they undergo over their lifetime.[2,3] The goal of the As Low As Reasonably Achievable (ALARA) radiation exposure principle includes the three basic strategies of decreasing time, increasing distance and using shielding to reduce radiation exposure. Multiple government agencies have education for both patients and physicians, focused on making sure imaging is necessary and uses the lowest dose of radiation possible.[4–6]

The growing use of imaging and interventional procedures that depend on ionizing radiation has raised concerns about the potential rise in occupational exposure to ionizing radiation among health care professionals. Radiology, cardiology, pulmonology, critical care, radiation oncology, thoracic surgery, orthopaedic surgery and anesthesiology

are specialties that use fluoroscopy or other radiation-creating equipment regularly, thereby exposing health care professionals and staff in those specialties to radiation regularly. A study that assessed the occupational radiation exposure of doctors over a 25-year period at a National Health Services teaching hospital found that the occupational radiation exposure of radiologists and cardiologists, as measured by body and collar dosimeters, has decreased over the 25-year period.[7] There was a decrease in ionizing radiation exposure to the eye in the cardiologists' cohort, but an increase in ionizing radiation exposure to the eye in the radiologists' cohort.[7] Definitive trends in the surgeon/anesthesiologists' group were more difficult to establish, but there was a significant decrease in exposure demonstrated by body and hand dosimeter measurements, but an increase in eye exposure.[7]

Radiation suites are not the only areas where diagnostic imaging occurs in health care settings. For example, in emergency departments (EDs) portable X-rays are frequently done. A recent study found the radiation levels in a level 1 trauma ED to be well-below the limit and thus noted that specific safety interventions were unwarranted.[8] Furthermore, intraoperative imaging is playing a larger role with the rise of minimally invasive surgeries such as spinal procedures. Because direct visibility is not possible in these surgeries, spine surgeons rely on intraoperative imaging to confirm proper placement of medical devices.[9] With the use of ionizing radiation spanning multiple specialties outside of radiology, finding unifying guidance is difficult.

Measuring Radiation Exposure

Measuring radiation released from a machine is quite easy; measuring radiation absorbed into an organ is much more difficult.[10] Measuring radiation dose in an organ is not practical, so calculations are done to determine the dose estimate, which is the product of the radiation measurement from the machine and various factors to account for different organs. Placing one dosimeter inside and another outside a lead apron provides an assessment of exposure. The exposure of the outside dosimeter is a surrogate for exposure to those unprotected areas (i.e., the head and hands) and the one inside represents exposure to protected areas (i.e., heart, thyroid, genitals).

The International Commission on Radiological Protection has dose limits on occupational exposure: 20mSv/yr averaged over a 5-year defined period with no single year exceeding 50 mSv.[11] A 2010 Korean study found that the average yearly radiation dose under the apron for interventional pain specialists was 1.08 mSv and 20.32 mSv over the collar.[12] A British study looking at 25-years of radiation exposure found the yearly dose to be <1 mSV on body dosimeters and 3.17-5.12 mSv on dosimeters in unprotected areas (e.g., hands).[7] It is clear that personal protective equipment (PPE) works when it is consistently used correctly. When environmental safety factors are employed (e.g., C-arm positioning) along with the ALARA principle, a physician's radiation exposure can stay within the allowable limits.

HEALTH EFFECTS

The ill effects of high-dose radiation are generally understood, but the consequences of long-term exposure to low-dose radiation are not as well-delineated. While data suggests that health care professionals exposed to ionizing radiation may experience an increased risk of cancer, cardiovascular disease, reproductive health effects, and the development of cataracts, the use of protective measures significantly reduces these risks.

Cancer

Although there is substantial evidence that exposure to ionizing radiation at moderate to high levels is associated with cancer, there is only limited information regarding risks at lower radiation doses. A review article examining 16 epidemiological studies published between 1975 and 2019, which looked at cancer risks in medical professionals exposed to ionizing radiation, found that medical personnel exposed to radiation before 1950, or those involved in fluoroscopically guided interventional procedures or radionuclide treatments, have higher cancer risks.[13] However, the strength of the evidence is moderate due to methodological limitations.

Cardiovascular Disease

A recent systematic review and meta-analysis examining 93 studies found that exposure to low doses of ionizing radiation is linked to an increased risk of cardiovascular disease (CVD) in a dose-dependent manner.[14] However, more research is needed to determine the exact relationship between low-dose ionizing radiation exposure and CVD risk

and to identify the underlying biological mechanisms. A 2024 meta-analysis of 27 articles also looked at low-dose radiation and cardiovascular effects.[15] Only one of the 27 studies included looked at physicians, but it found that compared to control individuals, physicians exposed to radiation had higher rates of capillary changes which may indicate early vascular damage.[15]

Radiation-induced cataracts

The lens of the eye is among the most radiosensitive tissues and radiation-induced cataracts have long been recognized. However, consensus is lacking on the radiation exposure threshold responsible for cataract formation.[9] A systematic review and meta-analysis assessing the risk of developing a radiation-induced cataract in interventional cardiologists (ICs) found that posterior lens opacity was significantly higher in interventional cardiologists relative to the control group, suggesting that ICs are at high risk of developing radiation-induced cataracts.[16] Similarly, a systematic review found increased risk of occupational cataract in health care professionals operating medical imaging.[17] The study also found a dose-response relationship between ionizing radiation exposure and the prevalence of opacities.[17] An epidemiological study examining the risk of radiation-induced cataracts in ICs compared 106 exposed cardiologists to 99 unexposed non-medical workers and found a significantly higher rate of cataracts among the cardiologists, with 18 percent showing posterior subcapsular lens opacities, compared to only five percent in the control group.[18]

Reproductive Health

The reproductive system is especially vulnerable to ionizing radiation. Spermatogenic cells are particularly sensitive to radiation, and exposure can lead to varying degrees of infertility, depending on the dose received. Ionizing radiation also poses significant risks to female reproductive health due to the high radiosensitivity of ovarian follicles and the hormonal networks that regulate fertility.[19] Prenatal radiation exposure significantly increases the risk of miscarriage, stillbirths, and congenital anomalies.[20] There is some evidence that radiation safety concerns disproportionately deter women from pursuing specialties like interventional cardiology.[21,22] Sixty cardiologists who were pregnant as trainees reported higher rates of obstetrical complications compared to those reported among women in the general population:15 percent experienced miscarriage, eight percent low birth weight, three percent pre-term delivery, and seven percent other complications like pre-eclampsia, eclampsia and emergent C-section.[23] However, it is unclear what aspects of the training (e.g., radiation exposure, physical demands) are responsible for this increase as a 2013 study among medical and surgical residents found similar complication rates.[24] Interestingly, in the 2024 survey of cardiology trainees, most reported access to well-fitted lead, radiation shields, and dosimeters; however, they lacked access to dosimetry data.[23]

REDUCING OCCUPATIONAL RADIATION EXPOSURE

Ways to reduce occupational exposure include time, distance and shielding. Shielding involves PPE, traditionally lead aprons, but there are other environmental methods like shields within the room. In looking at wearable PPE, a survey in Ireland revealed that most centers (72 percent) had only medium and large sized lead aprons, making arm-hole gaps and radiation of sensitive tissues a concern in those facilities.[25] Besides fit, there is concern for the weight of traditional lead aprons and how that weight can cause musculoskeletal problems in physicians over time, with several studies finding that operators in cardiac catheterization labs suffer from spinal problems.[26–29] Wearing lead aprons throughout a surgery that may take several hours or more is physically demanding and may cause some to question the benefit-risk ratio of PPE.[9] There has been interest in finding lighter-weight options that are just as effective. In one study, spine surgeons evaluated three types of non-lead materials and found the most effective one was only 30-40 percent of the weight of lead.[30] Another study found that non-lead aprons in general seemed to perform as well and were noted to be lighter.[31]

Some PPE, while considered effective, are often not used or used correctly, such as radiation glasses. For instance, one study found that PPE use was inconsistent and not always available (e.g., lead glasses were consistently used 10.2 percent and never used 61.1 percent of the time).[32] The same study found all forms of PPE were inconsistently used by 92.6 percent of participants and women were 4.3 times more likely to report that PPE was not available. Importantly, it has been suggested that PPE compliance was related to fit and availability.[33] Likewise, a study of orthopedic trainees found that reported barriers to PPE usage included lack of availability and perceived impracticality.[34] Finally, there is some evidence that inventorying and ensuring the availability of safety equipment,

hands-on instruction to complement traditional didactics, lowering default frame rates, and converting to real-time dosimetry may reduce radiation exposure among vascular surgery trainees.[35]

Educational gaps and professional society guidance

With the exception of trainees in radiologic fields, the Accreditation Council for Graduate Medical Education (ACGME) is relatively silent on educating trainees on radiation safety. For Diagnostic Radiology training programs, there is an ACGME directive on education for radionucleotide handling, but no specific requirements for radiation exposure safety. Other Radiology-based training programs have education on radiation safety listed, but other affected specialties, like cardiology, do not have it listed as a specific milestone requirement.[36] Training programs are left to develop their own guidance, leading to inconsistent education among trainees.[37]

Multiple national medical specialty societies have developed guidance for physicians and other health care professionals impacted by ionizing radiation (Appendix I). Medical physicists and radiation safety officers (RSOs) play a role in the development and maintenance of radiology suites. The American College of Radiology has created a manual for RSOs which addresses occupational exposure to ionizing radiation. RSOs play a key role in making sure policies are developed and implemented. The American College of Radiology-American Association of Physicists in Medicine's joint 2021 guidelines state that RSOs should have the "knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant."[38]

IONIZING RADIATION REGULATORY LANDSCAPE

The regulatory framework around ionizing radiation protection, use, disposal, safety, and monitoring is a patchwork of international guidance, federal, state, and local regulation and standards, as well as non-governmental and specialty society guidance.

International Standards

The International Atomic Energy Agency (IAEA) provides high level guidance on radiation safety regulations and standards.[39] In 2006, the IAEA published the IAEA Safety Standards Series No. SF-1, which sets out the fundamental principles of protection and safety with an emphasis on the protection of human health and the environment from the hazardous effects of ionizing radiation.[40] These principles are further reinforced through the International Basic Safety Standards (BSS), which regulate radiation dose limits, protection procedures, and monitoring mechanisms across multiple sectors, including health care.[41] Similarly, the World Health Organization (WHO), the Joint Commission, and the International Commission on Radiological Protection (ICRP) provide guidelines on radiation safety in medical practice.[42–45] The WHO establishes maximum allowable radiation doses for both patients and medical personnel to mitigate harmful side effects. The WHO also leads the Global Initiative on Radiation Safety in Health Care Settings to mobilize the health sector towards safe and effective use of radiation in medicine, which provides a platform for collaboration between health authorities, radiation protection regulators, international agencies, professional societies, patient networks, and scientific bodies.[46] The ICRP provides safety guidance for medical applications, including dose monitoring and strategies for reducing radiation exposure.[44] The Joint Commission outlines radiation risks of diagnostic imaging and fluoroscopy and includes standards around radiation safety for healthcare organizations to meet accreditation requirements.[45]

Federal Legislation and Administrative Landscape

There is copious federal legislation that outlines how multiple agencies, departments, councils, institutes, and commissions are responsible for setting requirements for use, storage, disposal, monitoring, auditing, and incident reporting of nuclear materials. (Appendix II). The result is a patchwork of entities overseeing different facets of nuclear material regulation in the United States. Although the federal regulatory landscape is complicated, the agencies most closely connected to radiation safety in health care settings and their respective roles are listed below:

- Nuclear Regulatory Commission (NRC) regulates civilian use of radioactive materials through licensing, setting dose and exposure limits, implementing monitoring, labeling, and notice requirements, and issuing penalties for noncompliance.[47]

- Environmental Protection Agency (EPA) sets generally applicable standards on the radioactivity in soil, water and air and provides federal guidance on recommendations for radiation protection including standardized dose limits, methods for dose and risk assessment.[48]
- Food and Drug Administration (FDA) regulates the manufacture, safety, and maintenance of medical devices that make or use radiation, electronic devices that emit radiation, and radiopharmaceuticals.[6,49,50]
- Occupational Safety and Health Administration (OSHA) sets standards for radiation protection in the workplace including exposure limits, exposure monitoring requirements, notification about radioactive hazards, and recordkeeping about radioactive hazards and exposures.[51]
- Department of Energy (DOE) oversees the treatment and disposal of much of the country's radioactive waste and is responsible for siting, building, and operating a geologic repository to dispose of nuclear waste.[52,53]
- National Institutes for Occupational Health and Safety (NIOSH) conducts epidemiological studies of the health effects of occupational exposure to ionizing radiation and evaluates exposures to ionizing radiation and reconstructs occupational radiation dose for certain workers with cancer who file claims under the Energy Employees Occupational Illness Compensation Program Act.[54,55]
- The National Council on Radiation Protection & Measurements (NCRP) formulates and disseminates information, guidance and recommendations on radiation protection and measurements.[56]

More detailed information about key legislation, statutory authority, published guidance reports, and agency, department, council, institute, and commission roles can be found in Appendices III, IV, V, and VI.

Interagency collaboration

There is a significant overlap in the radiation safety and protection work done by the agencies outlined above, which necessitates extensive agency collaboration. The Interagency Steering Committee on Radiation Standards (ISCORS) is comprised of eight Federal agencies, three Federal observer agencies and two state observer agencies. ISCORS facilitates consensus on acceptable levels of radiation risk to the public and workers and promotes consistent risk approaches in setting and implementing standards for protection from ionizing radiation.[57]

Despite collaborative efforts like ISCORS, interagency discrepancies still arise. For instance, OSHA's Ionizing Radiation standard (29 CFR part 1910) has not been revised from its original version, whereas the DOE (10 CFR part 835) and the NRC (10 CFR part 20) both have updated standards based on more recent radiation protection guidance from the ICRP (Publications 60, 26 and 30).[58–63] Consequently, many states, DOE, and NRC have cumulative annual dose limits, whereas OSHA uses quarterly dose limits. Specifically, each worker who is expected to receive more than 10 percent of the applicable annual dose limit (NRC) or more than 25 percent of the quarterly dose limit (OSHA) is required to wear one or more dosimeters. In response, OSHA issued a letter of interpretation explaining if an employer complied with the more current regulation at 10 CFR part 20 that it would be considered a de minimis condition because that standard is as or more protective than the OSHA standard. Additionally, OSHA's dose limits are not different for pregnant workers compared to other workers. However, NCRP, ICRP, and the Conference of Radiation Control Program Directors (CRCPD) have each recommended lower doses for the fetus of workers exposed to radiation.[58,64]

Memorandums of Understanding (MOUs) are another mechanism of collaboration to facilitate efficient and effective radiation safety and protection between agencies. (Appendix VII). For instance, NRC and OSHA both have authority over occupational safety and health at NRC-licensed facilities; however, identifying boundaries between the nuclear and radiological safety that NRC regulates and industrial safety and health that OSHA regulates can be complicated.[65] The NRC is responsible for radiation and chemical hazards produced by radioactive materials and facility conditions that affect the safety of radioactive materials. However, NRC licensees are required to comply with OSHA's standards and regulations for all other conditions and OSHA has authority to regulate employee exposures from all radiation sources not regulated by the NRC (e.g., X-ray equipment, linear accelerators, accelerator-produced radioactive materials, electron microscopes, ion implanters, and naturally occurring radioactive materials).[65] Collectively the NRC and OSHA regulations establish: dose limits for staff; requirements for the wearing of dosimeters; requirements for the posting of warning signs; requirements for periodic employee training and hazard communication; requirements for comprehensive record keeping for exposure monitoring results; periodic facility radiation safety assessments and preventive interventions; and requirements for timely reporting of results of exposure monitoring and exposure incidents to individual employees, including exposures to staff that exceed regulatory limits.[59,60,65]

The federal regulatory landscape provides high-level standards (e.g., licensure requirements, exposure limits, use of PPE and dosimeters, and regular survey and recordkeeping) as well as nonbinding guidance on how to implement those standards. (Appendix III). However, in many cases it is the states, RSOs, and health care institutions that determine what implementation and operationalization of those regulations looks like.

State Legislative Efforts

States also play a significant role in the regulation of occupational exposure to ionizing radiation. Most states have a radiation control agency and/or radiation protection program, responsible for regulating radiation-producing machines (e.g., x-rays and linear accelerators)[51] In NRC agreement states, these agencies also regulate radioactive materials [51] Some states also regulate occupational exposure to ionizing radiation in part through licensing and certification of medical imaging and radiation therapy professionals. In addition, there are instances where Agreement States or those with State Plans, each as described below, take on the regulatory responsibilities of agencies like the NRC and OSHA within their state boundaries.[66,67] More information about state specific regulations, licensing, state radiation programs, and implementation is in Appendix VII.

NRC Agreement States have entered into an effective regulatory discontinuance agreement with the NRC, which allows them to regulate occupational exposure to radioactive materials within their borders. Agreement States exercise licensing, regulatory, and enforcement actions under direction of the governors in a manner that is compatible with the licensing and enforcement programs of the NRC. There are 39 NRC Agreement States, which administer about 75 percent of the more than 20,000 active source, byproduct, and special nuclear materials licenses in place in the United States.[68] The NRC periodically reviews the performance of each Agreement State to assure compatibility with NRC's regulatory standards. Other collaborative efforts between the NRC and Agreement States include: (1) National Materials Program (NMP), which is the collective framework of the NRC and Agreement States; (2) the Integrated Materials Performance Evaluation Process (IMPEP), which ensures uniform nationwide regulation by reviewing the regulatory performance of both the NRC and the States using a common set of performance criteria; and (3) The Office of Nuclear Material Safety and Safeguards (NMSS), which establishes and maintains communications and working relationships between the NRC and States, local government, other Federal agencies and Native American Tribal Governments.[66,69,70]

Like NRC Agreement States, some states have OSHA approved State Plans in lieu of direct OSHA oversight. OSHA State Plans are required to have standards and enforcement programs that are at least as effective as OSHA's and may have different or more stringent requirements. There are 29 OSHA-approved State Plans operating state-wide occupational safety and health programs.[71]

Non-Governmental Guidance

In addition to the role of the federal and state legislative and agency oversight, there is also significant non-governmental guidance. The Conference of Radiation Control Program Directors (CRCPD) is a non-governmental nonprofit comprised primarily of state and local government radiation professionals (e.g., directors and staffs of regulatory programs from both Agreement and non-Agreement States) that regulate the use of radiation sources.[72,73] As such, the CRCPD provides a forum for the states to interact with the NRC and coordinate the regulation of radioactive materials that are not governed by the Atomic Energy Act (AEA). CRCPD has five councils and more than 70 working groups that research a variety of topics pertinent to radiation protection. Similarly, the Organization of Agreement States (OAS) is a professional organization that includes the directors and staff of Agreement State programs. OAS was established to facilitate communication between the NRC and the Agreement States. Both the CRCPD and the OAS participate in the National Materials Program. Additionally, the National Academy of Sciences (NAS) and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) publish a series of reports that provide much of the data used in setting radiation standards.[74] Finally, as noted above medical specialty societies also play an important role in providing guidance and setting policy on radiation safety in health care settings. (Appendix I)

Regulatory standards and guidance for radiation safety in health care settings

There is extensive federal, state, and local regulation of radiation safety in health care settings along with non-binding guidance and technical reports from international organizations, non-governmental organizations, and medical specialty societies. In general, the federal regulations provide high-level standards for the structure and function of a radiation protection program, but the implementation of those standards is often determined by the state regulations and the RSO with guidance from a variety of sources (e.g., ICRP, NMP, NMSS, OAS, CRCPD, NCRP, EPA,).

For instance, in order to obtain a license, either from the NRC or an Agreement State the facility must have a radiation protection program as outlined in 10 CFR Part 20.[60] At a minimum, a radiation protection program should include the following:

- Qualified staff (e.g., radiation safety officer, medical physicist, nuclear pharmacist).[75]
- Standard procedures (e.g., PPE that fits, a dosimetry program, area monitoring and surveys), engineering and administrative controls (e.g., proper labeling, shielding, interlock systems), and radiological controls (e.g., entry and exit controls, receiving, inventory control, storage, and disposal) to facilitate occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).[58–61,76]
- Worker training on radiation protection, including health effects associated with ionizing radiation dose, and radiation protection procedures and controls to minimize dose and prevent contamination.[59,76]
- Emergency procedures to identify and respond to radiological emergency situations.
- Recordkeeping and reporting programs (e.g., dosimetry reports, notifications), internal audits, and regular external review (at least annually) of the radiation protection program content and implementation.[51,60,61,77]

However, the details of the type of PPE, dosimeters, manner of training, and methods for ensuring correct use are not outlined in the regulation. For instance, the regulation requires PPE that fits and is suitable for the assessed hazards; however, it does not necessarily stipulate lead aprons or protective glasses. Similarly, dosimeters are required, but the type and number used are up to the employer. This highlights the importance and value of uniform education and training standards for RSOs, and consistent guidance from medical specialty societies and international, federal, interstate, and non-governmental organizations.

CONCLUSION

Ionizing radiation can have harmful health effects; however, the evidence on the health effects of low-dose and very-low dose occupational radiation exposure in health care facilities is limited. This is especially true as it relates to physicians and other health care professionals. Despite the limited evidence on negative health effects associated with low-dose and very-low dose occupational radiation exposure in health care facilities, the precautionary principle as well as international guidance, federal and state regulation, and non-governmental and specialty society guidance supports continued use of PPE that appropriately fits and covers all body types, genders, and pregnancy statuses as well as continued education and training on ways to reduce exposure. At the same time, continued research into the health effects of low level and very-low level ionizing radiation, the effectiveness of personal protective equipment and engineering controls designed to reduce exposure, and ways to improve PPE use fidelity are needed.

CURRENT AMA POLICY

Current AMA policy encourages public and private healthcare institutions to ensure comprehensive coverage of different body types by providing readily available PPE that reduces exposure to as low as reasonably achievable for employees of all genders and pregnancy statuses. Additional policies are primarily focused on protecting patients from ionizing radiation. (See Appendix VIII).

RECOMMENDATIONS

Your Council on Science and Public Health recommends that the following be adopted and the remainder of this report be filed.

That Policy H-455.975, "Regulation of Ionizing Radiation Exposure for Health Care Workers" be amended by addition and deletion to read as follows:

1. Our American Medical Association encourages: (1) public and private health care institutions to ensure the availability of personal protective equipment (PPE) that provides comprehensive coverage of different body types ~~by providing readily available PPE that reduces~~ to reduce ionizing radiation exposure to as low as reasonably achievable for ~~employees~~ health care personnel and trainees of all genders and pregnancy statuses; (2) the use of dosimetry badges for all health care personnel and trainees who work in expore prone settings, with clear follow-up actions for those with elevated cumulative exposure; (3) continued research on the health effects of low level and very-low level exposure to ionizing radiation, the effectiveness of PPE and administrative and engineering controls designed to reduce exposure (e.g., shielding, interlock systems, labeling,), barriers to PPE use (e.g., fit, availability, cost), and ways to improve PPE use fidelity (e.g., training, education, and access to appropriately sized and ergonomic PPE); (4) education for all health care personnel and trainees specific to their expected exposure to ionizing radiation that includes awareness of and methods to limit radiation exposure to both patients and clinicians. Training programs should provide education specific to their specialties so trainees know which protective equipment and controls their facilities should have in place and know how to use them correctly; and (5) collaboration between medical specialty societies to establish education and training standards for the use of PPE and engineering controls to reduce exposure to ionizing radiation for health care personnel and trainees..
2. ~~Our AMA will work with the appropriate and interested parties to study how best to accomplish comprehensive protection from ionizing radiation for employees, taking into account variation in body types, pregnancy status, specifics of procedures being performed, as well as how exposure can be limited beyond PPE (personal protected equipment), with report back at I-25~~.

Fiscal Note: Minimal – less than $1,000.

APPENDIXES

Appendix I: Specialty Societies Providing Guidance on Radiation Safety and PPE

American Academy of Orthopaedic Surgeons[78] – Educational Materials and Articles[79]
American Association of Neurologic Surgeons[80]
American Association of Physicists in Medicine[81]
American College of Cardiology[82] – Consensus statement[83], Educational Materials[84] and JACC articles[26]
American College of Chest Physicians[85]
American College of Nuclear Medicine[86]
American College of Radiation Oncology[87] – Policy Statement on Radiation Therapy Supervision[88]
American College of Radiology[89] - Manual for Radiation Safety Officers[2]
American College of Surgeons[90]
American Orthopaedic Association[91]
American Orthopaedic Foot & Ankle Society[92]
American Roentgen Ray Society[93] - Webinars[94]
American Society of Anesthesiologists[95]
American Thoracic Society[96]
Association of Academic Radiology[97]
Association of Program Directors in Vascular Surgery[98] – Guidance for pregnant trainees[99]
Congress of Neurological Surgeons[100]
Health Physics Society[101] – Positions and Position Statements[102,103]
North American Spine Society[104] - Educational Materials[105]
Radiological Society of North America[106] - Educational Materials[107]

Society for Cardiovascular Angiography and Interventions[108] – Educational Materials[109] and a Campaign on Women and Safety[110]
Society for Pediatric Radiology[111]
Society of Critical Care Medicine[112]
Society of Interventional Radiology[113] - Toolkits[114]
Society of Nuclear Medicine and Molecular Imaging[115]
Society of Thoracic Surgeons[116]

Appendix II: Key Federal Legislation on Radiation[117,118]

Atomic Energy Act of 1954, as Amended[119]	The Atomic Energy Act (AEA) is the fundamental U.S. law on both the civilian and the military uses of nuclear materials. On the civilian side, it established the Atomic Energy Commission (AEC) to provide for both the development and the regulation of the uses of nuclear materials and facilities in the United States. The ensuing amendments and consequent legislation delegate regulatory authority to the NRC, EPA, and DOE. The AEA also authorizes States to adopt equivalent or more stringent alternatives to the Federal health and environmental protection standards with respect to byproduct material.
Energy Reorganization Act of 1974, as amended[120]	The Energy Reorganization Act split the functions of the AEC. The DOE was assigned responsibility for the development and production of nuclear weapons, promotion of nuclear power, and other energy-related work. The NRC was assigned the regulatory authority for civilian nuclear activities. Later amendment to the Act also provided protections for employees who raise nuclear safety concerns.
Reorganization Plans[121]	Reorganization Plan No. 3 of 1970 established the EPA and gave it a role in establishing "generally applicable environmental standards for the protection of the general environment from radioactive material." Reorganization Plan No. 1 of 1980 strengthened the executive and administrative roles of the NRC Chairman. This Reorganization Plan also provided that all policy formulation, policy-related rulemaking, and orders and adjudications would remain vested with the full Commission.
Radiation Control for Health and Safety Act of 1968[122]	Under the Radiation Control for Health and Safety Act, the FDA (via amendments to Section 531-542 of the FD&C Act) is responsible for developing and administering performance standards, monitoring compliance, and conducting research for these electronic products including those in the medical sphere like diagnostic x-ray or ultrasound imaging devices, microwave or ultrasound diathermy devices, microwave blood warmers or sterilizers, laser coagulators, ultrasound phacoemulsifiers, x-ray or electron accelerators, sunlamps, ultraviolet dental curing devices,
Nuclear Waste Policy Act of 1982[123]	The Nuclear Waste Policy Act of 1982 delineates responsibilities of the DOE, NRC, and EPA with respect to nuclear waste treatment, disposal, and management. DOE has the responsibility to site, construct, operate, and close a repository for the disposal of spent nuclear fuel and high-level radioactive waste. EPA sets public health and safety standards for releases of radioactive materials from a repository. NRC promulgates regulations governing construction, operation, and closure of nuclear waste repositories.
Low-Level Radioactive Waste Policy Amendments Act of 1985[121]	The Low-Level Radioactive Wast Policy Amendments Act gives States the responsibility to dispose of low-level radioactive waste generated within their borders and allows them to form compacts to locate facilities to serve a group of States. The Act also requires the NRC to establish standards for determining when radionuclides are present in waste streams in sufficiently low concentrations or quantities as to be below regulatory concern.
Clean Air Act[124]	The Clean Air Act gives the federal government authority to regulate and limit air emissions and pollution. It authorizes EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and public welfare and to regulate emissions of hazardous air pollutants (HAPs). Some HAPs are radionuclides.

Clean Water Act[125]	The Clean Water Act regulates the discharges of pollutants, including some radionuclides, into the waters of the United States. It authorizes EPA and states to set and enforce quality standards for surface waters.
Energy Policy Act[126]	The Energy Policy Act requires EPA to promulgate standards to ensure protection of public health from high-level radioactive wastes in a deep geologic repository that might be built under Yucca Mountain in Nevada.
The Safe Drinking Water Act[127]	The Sage Drinking Water Act requires EPA to set legal limits on the levels of certain radionuclides in drinking water.
Administrative Procedure Act (5 U.S.C. Chapters 5 through 8)[128]	This Act is the fundamental law governing the processes of Federal administrative agencies. Its original focus was on rulemaking and adjudication. It requires, for example, that affected persons be given adequate notice of proposed rules and an opportunity to comment on the proposed rules and that, in cases in which another statute requires that the agency provide a hearing "on the record," the parties are given adequate opportunity to present facts and argument and the hearing officer is impartial. The Act gives interested persons the right to petition an agency for the issuance, amendment, or repeal of a rule. It also provides standards for judicial review of agency actions.
National Environmental Policy Act[129]	Every proposal for a major Federal action significantly affecting the quality of the human environment requires a detailed statement on, among other things, the environmental impact of the proposed action and alternatives to the proposed action.

Appendix III: Federal Agency Roles Regarding Ionizing Radiation

NRC	10 CFR Part 20 authorizes the NRC to regulate civilian use of radioactive materials (e.g., source material, special nuclear materials, and byproduct material) for things like commercial nuclear power plants and nuclear medicine through licensing, setting dose and exposure limits, implementing monitoring, labeling, and notice requirements, and issuing penalties for noncompliance.
EPA	40 CFR Part 191 authorized the EPA to set generally applicable standards on the radioactivity in soil, water and air that comes from human use of radioactive elements for the protection of human health and the environment from radioactive materials. In addition to setting legally enforceable standards, the EPA issues federal guidance and technical reports with recommendations on radiation protection (e.g., standardized dose limits, methods for dose and risk assessment), which are used by federal and state agencies in developing radiation regulations and standards.
FDA	21 CFR Parts 892 and 1020 gives the FDA authority to regulate the manufacture, safety, and maintenance of medical devices (e.g., linear accelerators, radiography, fluoroscopy, and CT equipment), electronic devices that emit radiation, and radiopharmaceutical through the Radiological Health Program and the Center for Devices and Radiological Health.[6,49,50,130] However, the States regulate the operation of these devices. FDA also publishes guidance documents that represent FDA's current thinking on a topic and provides a suggested or recommended approach to meet the requirements of a regulation or statute. The guidance documents are not legally binding, but they are a suggested or recommended approach to meet the requirements of a regulation or statute.
OSHA	29 CRF 1910 authorizes OSHA to set standards for radiation protection in the workplace. This includes setting exposure limits, monitoring exposure with personnel monitoring equipment (e.g., film badges, pocket chambers, pocket dosimeters, or film rings), posting signage to notify employees of radiation and radioactive areas, disposal of radioactive, and recordkeeping. 29 CRF 1910 also requires, "protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protectives shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition." It is incumbent upon the employer to assess hazards, communicate to employees that these hazards exist, provide PPE that properly fits each employee, and train employees on appropriate use. Examples of commonly used PPE for radiation protection from X-rays and gamma rays include lead aprons/vests, lead thyroid collars, lead gloves, and safety goggles
DOE	The DOE is responsible for managing much of the country's tries radioactive waste (e.g., providing a repository for high-level waste, operating the Waste Isolation Pilot Plant (WIPP), and providing a disposal option for the portion of the NRC-regulated low-level waste that is not generally suitable for near-surface disposal). 10 CFR 961 establishes the contractual terms and conditions under which the Department of Energy (DOE) will make available nuclear waste disposal services. 10 CFR 835

	establishes radiation protection standards, limits, and program requirements for protecting individuals from ionizing radiation resulting from the conduct of DOE activities.
NIOSH	The NIOSH mission is to develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice.[55] To facilitate this the NIOSH Division of Field Studies and Engineering, Field Research Branch conducts epidemiological studies of the health effects of occupational exposure to ionizing radiation and evaluate exposures to ionizing radiation. Similarly, the NIOSH Division of Compensation Analysis and Support reconstructs occupational radiation dose for certain workers with cancer who file claims under the Energy Employees Occupational Illness Compensation Program Act.[131,132]
NCRP	The National Council on Radiation Protection and Measurements (NCRP) seeks to formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific thinking. The primary statutory goals of the NCRP under Public Law 88-376 are to: (1) collect, analyze, develop and disseminate in the public interest information and recommendations about protection against radiation and radiation measurements; (2) provide a means by which organizations concerned with the scientific and related aspects of radiation protection and of radiation quantities, units and measurements may cooperate for effective utilization of their combined resources, and to stimulate the work of such organizations; (3) develop basic concepts about radiation quantities, units and measurements, about the application of these concepts, and about radiation protection; and (4) cooperate with the International Commission on Radiological Protection, the Federal Radiation Council, the International Commission on Radiation Units and Measurements, and other national and international organizations, governmental and private, concerned with radiation quantities, units and measurements and with radiation protection.[133] The NCRP has 138 reports and commentaries, but those reports require purchase.[134] Only their annual meeting proceedings and statements are free to the public.

Appendix IV: Code of Federal Regulations Authority and Statutory Language on Radiation Safety and Exposure Guidance

10 CFR Part 20[60]

§ 20.1003 Definitions.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in table 1, columns 1 and 2 of appendix B to §§ 20.1001-20.2401).

. . .

§ 20.1101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

. . .

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of—

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

. . .

§ 20.1501 General.

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that—

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate—

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

(c) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(d) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor

10 CFR Part 35[76]

§ 35.2 Definitions.

Associate Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on—

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Authorized medical physicist means an individual who—

(1) Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on—

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who—

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on—

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who—

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on—

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or

(2) Is identified as a Radiation Safety Officer on—

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)

(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)

(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)

(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or an Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c)

(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material licensee. The individual must also meet the requirements in paragraph (d) of this section.

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized

medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

CFR 10 Part 835[61]

§ 835.1 Scope.

(a) ***General.*** The rules in this part establish radiation protection standards, limits, and program requirements for protecting individuals from ionizing radiation resulting from the conduct of DOE activities.

(b) ***Exclusion.*** Except as provided in paragraph (c) of this section, the requirements in this part do not apply to:

(1) Activities that are regulated through a license by the Nuclear Regulatory Commission or a State under an Agreement with the Nuclear Regulatory commission, including activities certified by the Nuclear Regulatory Commission under section 1701 of the Atomic Energy Act;

(2) Activities conducted under the authority of the Deputy Administrator for Naval Reactors, as described in Pub. L. 98-525 and 106-65;

(3) Activities conducted under the Nuclear Explosives and Weapons Surety Program relating to the prevention of accidental or unauthorized nuclear detonations;

(4) DOE activities conducted outside the United States on territory under the jurisdiction of a foreign government to the extent governed by occupational radiation protection requirements agreed to between the United States and the cognizant government;

(5) Background radiation, radiation doses received as a patient for the purposes of medical diagnosis or therapy, or radiation doses received from participation as a subject in medical research programs; or

(6) Radioactive material on or within material, equipment, and real property which is approved for release when the radiological conditions of the material, equipment, and real property have been documented to comply with the criteria for release set forth in a DOE authorized limit which has been approved by a Secretarial Officer in consultation with the Director, Office of Environment, Health, Safety and Security.

(7) Radioactive material transportation not performed by DOE or a DOE contractor.

(c) Occupational doses received as a result of excluded activities and radioactive material transportation listed in paragraphs (b)(1) through (b)(4) and (b)(7) of this section, shall be included to the extent practicable when determining compliance with the occupational dose limits at §§ 835.202 and 835.207, and with the limits for the embryo/fetus at § 835.206. Occupational doses resulting from authorized emergency exposures and planned special exposures shall not be considered when determining compliance with the dose limits at §§ 835.202 and 835.207.

(d) The requirements in subparts F and G of this part do not apply to radioactive material transportation by DOE or a DOE contractor conducted:

(1) Under the continuous observation and control of an individual who is knowledgeable of and implements required exposure control measures, or

(2) In accordance with Department of Transportation regulations or DOE orders that govern such movements.

§ 835.2 Definitions.

. . .

ALARA means "As Low As is Reasonably Achievable," which is the approach to radiation protection to manage and control exposures (both individual and collective) to the work force and to the general public to as low as is reasonable, taking into account social, technical, economic, practical, and public policy considerations. As used in this part, ALARA is not a dose limit but a process which has the objective of attaining doses as far below the applicable limits of this part as is reasonably achievable.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man (ICRP Publication 23) that would result in a committed effective dose of 5 rems (0.05 sieverts (Sv)) (1 rem = 0.01 Sv) or a committed equivalent dose of 50 rems (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and inhalation of selected radionuclides are based on International Commission on Radiological Protection Publication 68, *Dose Coefficients for Intakes of Radionuclides by Workers*, published July, 1994 (ISBN 0 08 042651 4). This document is available from Elsevier Science Inc., Tarrytown, NY.

Authorized limit means a limit on the concentration of residual radioactive material on the surfaces or within the property that has been derived consistent with DOE directives including the as low as is reasonably achievable (ALARA) process requirements, given the anticipated use of the property and has been authorized by DOE to permit the release of the property from DOE radiological control.

. . .

§ 835.202 Occupational dose limits for general employees.
(a) Except for planned special exposures conducted consistent with § 835.204 and emergency exposures authorized in accordance with § 835.1302, the occupational dose received by general employees shall be controlled such that the following limits are not exceeded in a year:
(1) A total effective dose of 5 rems (0.05 Sv);
(2) The sum of the equivalent dose to the whole body for external exposures and the committed equivalent dose to any organ or tissue other than the skin or the lens of the eye of 50 rems (0.5 Sv);
(3) An equivalent dose to the lens of the eye of 15 rems (0.15 Sv); and
(4) The sum of the equivalent dose to the skin or to any extremity for external exposures and the committed equivalent dose to the skin or to any extremity of 50 rems (0.5 Sv).
(b) All occupational doses received during the current year, except doses resulting from planned special exposures conducted in compliance with § 835.204 and emergency exposures authorized in accordance with § 835.1302, shall be included when demonstrating compliance with §§ 835.202(a) and 835.207.
(c) Doses from background, therapeutic and diagnostic medical radiation, and participation as a subject in medical research programs shall not be included in dose records or in the assessment of compliance with the occupational dose limits.

10 CFR Part 961[135]

§ 961.1 Purpose.
This part establishes the contractual terms and conditions under which the Department of Energy (DOE) will make available nuclear waste disposal services to the owners and generators of spent nuclear fuel (SNF) and high-level radioactive waste (HLW) as provided in section 302 of the Nuclear Waste Policy Act of 1982 (Pub. L. 97-425). Under the contract set forth in § 961.11 of this part, DOE will take title to, transport, and dispose of spent nuclear fuel and/or high-level radioactive waste delivered to DOE by those owners or generators of such fuel or waste who execute the contract. In addition, the contract will specify the fees owners and generators of SNF and/or HLW will pay for these services. All receipts, proceeds, and revenues realized by DOE under the contract will be deposited in the Nuclear Waste Fund, an account established by the Act in the U.S. Treasury. This fund will pay for DOE's radioactive waste disposal activities, the full costs of which will be borne by the owners and generators under contract with DOE for disposal services.

21 CFR 892[136]

§ 892.1 Scope.

(a) This part sets forth the classification of radiology devices intended for human use that are in commercial distribution.
(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.
(c) To avoid duplicative listings, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.
(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of this title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.

. . .

§ 892.3 Effective dates of requirement for premarket approval.
A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.
(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.
(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

21 CFR 1020[137]

§ 1020.31 Radiographic equipment.
The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

. . .

§ 1020.32 Fluoroscopic equipment.
The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

29 CFR Part 1904[77]

§ 1904.0 Purpose.
The purpose of this rule (part 1904) is to require employers to record and report work-related fatalities, injuries, and illnesses.

29 CFR Part 1910[59]

§ 1910.132 General requirements.

(a) **Application.** Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.

(b) **Employee-owned equipment.** Where employees provide their own protective equipment, the employer shall be responsible to assure its adequacy, including proper maintenance, and sanitation of such equipment.

(c) ***Design.*** All personal protective equipment shall be of safe design and construction for the work to be performed.

(d) ***Hazard assessment and equipment selection.***

(1) The employer shall assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). If such hazards are present, or likely to be present, the employer shall:

(i) Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;

(ii) Communicate selection decisions to each affected employee; and,

(iii) Select PPE that properly fits each affected employee.

(2) The employer shall verify that the required workplace hazard assessment has been performed through a written certification that identifies the workplace evaluated; the person certifying that the evaluation has been performed; the date(s) of the hazard assessment; and, which identifies the document as a certification of hazard assessment.

(e) ***Defective and damaged equipment.*** Defective or damaged personal protective equipment shall not be used.

(f) ***Training.***

(1) The employer shall provide training to each employee who is required by this section to use PPE. Each such employee shall be trained to know at least the following:

(i) When PPE is necessary;

(ii) What PPE is necessary;

(iii) How to properly don, doff, adjust, and wear PPE;

(iv) The limitations of the PPE; and,

(v) The proper care, maintenance, useful life and disposal of the PPE.

. . .

(h) ***Payment for protective equipment.***

(1) Except as provided by paragraphs (h)(2) through (h)(6) of this section, the protective equipment, including personal protective equipment (PPE), used to comply with this part, shall be provided by the employer at no cost to employees.

(2) The employer is not required to pay for non-specialty safety-toe protective footwear (including steel-toe shoes or steel-toe boots) and non-specialty prescription safety eyewear, provided that the employer permits such items to be worn off the job-site.

§ 1910.1096

(b) ***Exposure of individuals to radiation in restricted areas.***

(1) Except as provided in paragraph (b)(2) of this section, no employer shall possess, use, or transfer sources of ionizing radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from sources in the employer's possession or control a dose in excess of the limits specified in Table G-18:

TABLE G-18

	Rems per calendar quarter
Whole body: Head and trunk; active blood-forming organs; lens of eyes; or gonads	11/4
Hands and forearms; feet and ankles	183/4
Skin of whole body	71/2

. . .

(d) ***Precautionary procedures and personal monitoring.***

(1) Every employer shall make such surveys as may be necessary for him to comply with the provisions in this section. *Survey* means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

(2) Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment by:

(i) Each employee who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (b)(1) of this section; and

(ii) Each employee under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (b)(1) of this section; and

(iii) Each employee who enters a high radiation area.

40 CFR 191[138]

§ 191.03 Standards.

(a) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities regulated by the Commission or by Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from:

(1) Discharges of radioactive material and direct radiation from such management and storage and

(2) all operations covered by Part 190; shall not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other critical organ.

(b) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities for the disposal of such fuel or waste that are operated by the Department and that are not regulated by the Commission or Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from

discharges of radioactive material and direct radiation from such management and storage shall not exceed 25 millirems to the whole body and 75 millirems to any critical organ.

Appendix V: Agency Reports[134,139,140]

Federal Guidance Report No. 15[141]	Updates and expands the 1993 FDR No. 12 providing age-specific, reference person effective dose rate coefficients for 1,252 radionuclides based on external exposure to radionuclides distributed in air, water and soil for use in implementing radiation protection programs.	EPA - 2019
Federal Guidance Report No. 14[142]	Provides recommendations for keeping patients ionizing radiation doses as low as reasonably achievable without compromising the quality of patient care.	EPA - 2014
Federal Guidance Report No. 13[143]	Provides methods and data for estimating risks due to both internal and external radionuclide exposures. It includes coefficients for assessing cancer risks from environmental exposure to about 800 radionuclides. Both mortality and incidence risk coefficients are tabulated for inhalation, food and water ingestion, submersion in air and exposure to uniform soil concentrations. The age-averaged coefficients consider age-specific intake rates, dose modeling and risk modeling.	EPA - 1999
Federal Guidance Report No. 12[144]	The external dose coefficients in this report are intended for use by federal agencies having regulatory responsibilities for protection of members of the public and/or workers. We also encourage their use by state and local authorities. This document provides exposure-to-dose coefficients for general application based on the 1987 Federal Radiation Protection Guidance.	EPA - 1993
Radiation Protection Guidance to Federal Agencies for Occupational Exposure; Approval of Environmental Protection Agency Recommendations[145]	This guidance provides general principles and specifies the numerical primary guides for limiting worker exposure. It applies to all workers who are exposed to radiation in the course of their work, either as employees of institutions and companies subject to Federal regulation or as Federal employees.	EPA - 1987
Radiation Protection Guidance for Federal Agencies (Federal Radiation Council)[146]	This guidance presents recommendations for population groups exposed to environmental sources of radiation. It provides Radiation Protection Guides (RPG); guidance on general principles of control applicable to all environmental radionuclides; and specific guidance in connection with exposure of population groups to radium-226, iodine-131, strontium-90, and strontium-89.	EPA - 1961
Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)[147]	This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for the medical use of byproduct material.	NRC - 2019
REGULATORY GUIDE 8.4 - PERSONNEL MONITORING DEVICE—DIRECT-READING POCKET DOSIMETERS [148]	This guide provides guidance acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for use in complying with the NRC's regulations on direct-reading pocket dosimeters; it includes specific performance standards for personnel monitoring but not for area monitoring.	NRC - 2011
REGULATORY GUIDE 8.2 - ADMINISTRATIVE PRACTICES IN RADIATION SURVEYS AND MONITORING [149]	This guide provides guidance acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for use in complying with the NRC's regulations for administrative practices associated with surveys and monitoring of ionizing radiation in licensed institutions; it is intended primarily for administrative and	NRC - 2011

	management personnel in organizations that are involved in, or are planning to initiate, activities involving the handling of radioactive materials or radiation.	
REGULATORY GUIDE 8.18 - INFORMATION RELEVANT TO ENSURING THAT RADIATION EXPOSURES AT MEDICAL INSTITUTIONS WILL BE AS LOW AS IS REASONABLY ACHIEVABLE[150]	This guide is directed specifically toward medical licensees and recommends methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable to maintain exposures as low as is reasonably achievable (ALARA) in medical institutions.	NRC - 2011
Radiation Dose Estimates for Radiopharmaceuticals (NUREG/CR-6345)[151]	The dose estimates were calculated using the MIRD Technique as implemented in the MIRDOSE3 computer code, developed by Oak Ridge Institute for Science and Education, Radiation Internal Dose Information Center. In this code, residence times for source organs are used with decay data from the MIRD Radionuclide Data and Decay Schemes to produce estimates of radiation dose to organs of standardized phantoms representing individuals of different ages.	NRC 1996
Report No. 151: Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities.[152]	This Report presents recommendations and technical information related to the design and installation of structural shielding for megavoltage x- and gamma-ray radiotherapy facilities.	NRCP - 2005
Report No. 177: Radiation Protection in Dentistry and Oral & Maxillofacial Imaging.[153]	This Report provides radiation protection guidance for the use of x rays in dental practice, including the use of cone-beam computed tomography, digital-imaging devices, and handheld x-ray systems. The aim of this Report is to provide a practical radiation protection guide for dentists and their assistants. Information is presented in a clear and comprehensive format focusing on dental radiological practices.	NCRP - 2019
Report No. 148: Radiation Protection in Veterinary Medicine.[154]	Report No. 148 is concerned with the protection of individuals who may be exposed to radiation emitted by x-ray equipment and both sealed and unsealed radioactive sources in the practice of veterinary medicine. To the extent that the animal patient exposure is reduced, there is usually a proportional decrease in the occupational exposure to personnel. The Report provides guidance for the development of an effective radiation safety program and recommendations for the design of radiological facilities and for the use of radiographic, fluoroscopic and therapeutic equipment in veterinary medicine. Included are recommendations for the use of radiopharmaceuticals in diagnosis and therapy, and for the use of lasers and ultrasonic equipment.	NCRP - 2004
Report No. 147: Structural Shielding Design for Medical X-ray Imaging Facilities.[155]	Report No. 147 (2004) presents recommendations and technical information related to the design and installation of structural shielding for facilities that use x rays for medical imaging. The purpose of structural shielding is to limit radiation exposure to employees and members of the public.	NRCP - 2004
Report No. 144: Radiation Protection for Particle Accelerator Facilities.[156]	The Report revises and expands on the earlier report and includes new information on source intensities, shielding, dosimetry, and the environmental aspects of particle accelerator operation. It is primarily concerned with radiological safety aspects that are special to the operation of particle accelerators having energies above about 5 MeV up to the highest energies available, while not neglecting low-energy neutron generators. The purpose of this Report is to provide design guidelines for	NCRP - 2003

	radiation protection, and to identify those aspects of radiological safety that are of major, or even unique, importance to the operation of particle accelerator installations and to suggest methods by which safe operation may be achieved.	
Report No. 133: Radiation Protection for Procedures Performed Outside the Radiology Department.[157]	Report No. 133 (2000) is an 81 page document with five sections, two appendices, a glossary, and references. Section 1 introduces sources of occupational radiation exposure and compares occupational exposures in medicine with other sources of occupational exposure. Section 2 describes radiologic medical procedures that are often performed outside the radiology department and categorizes the procedures according to their potential for occupational exposure. Section 3 addresses conditions that affect potential occupational exposure such as time, distance, shielding, and orientation of radiation source, patient and operator. Section 4 addresses medical personnel monitoring and Section 5 briefly addresses the responsibility of management to provide safe conditions for both employees and patients.	NCRP - 2000

Appendix VI: Interagency MOUs regarding radiation safety[158,159]

OSHA and FDA (2024)[160]	The FDA and OSHA will share relevant information with each other, while ensuring that the exchange of such information complies with applicable law. If FDA, in its inspections of facilities, has reason to believe that a potential violation of an employer's obligations under the OSH Act or an OSHA standard or regulation has occurred, FDA will provide this information to OSHA to the extent that is feasible. If OSHA, in its investigations of facilities where FDA regulated products are produced, processed, manufactured or held has reason to believe that factors are present which may indicate a possible violation of FDA standards, OSHA will provide this information to FDA, to the extent feasible. The FDA and OSHA agree to maintain a practicable process including procedures and criteria for information sharing and a plan for implementation. The FDA and OSHA agree to develop and implement a plan for training appropriate employees based on the priorities and needs of each organization to meet the intention of this MOU.
DOE and EPA (2024)[161]	DOE will coordinate with EPA on the scope, objectives, research results, and associated funding of mutually agreed cooperative research and/or training activities. DOE will not make recommendations regarding future or potential EPA regulatory activities in response to technical information requests. EPA will provide oversight and direction of its own work, funding authorization, and mission and objectives. EPA will coordinate with DOE on the scope, objectives, research results, and associated funding of mutually agreed cooperative research and/or training activities. EPA will neither make recommendations regarding specific siting, design or facility concepts nor participate in any DOE site selection process.
NRC and FDA (2023)[162]	The NRC and the FDA agree to inform each other, as appropriate and permitted by law, as soon as possible, but no later than 30 calendar days whenever either agency identifies a significant product complaint, allegation, medical incident, or emergency that involves the products that are covered by this MOU or becomes aware through notification, inspection, or surveillance mechanisms at either agency of a significant potential public health problem such as a malfunction, failure, or medical incident involving a product covered by this MOU.

	The Parties may consider performing joint inspections or other collaborations when appropriate and as permissible by law, and as resources permit. In addition, both Parties will discuss providing technical expertise for planning, performance, or review in areas of mutual interest, subject to program priorities and availability of funds and personnel. FDA and NRC may assist each other to the extent appropriate and as permissible by law, and as resources allow, to investigate incidents, complaints, or other situations involving products covered by this MOU. Upon request by the FDA, the NRC will promptly notify NRC licensees and Agreement State Program Directors of any public health issues or other important user communications initiated by the FDA and intended for public dissemination. the FDA and the NRC may share information concerning jointly regulated products, new technology or methods under development or review, including devices for which regulations or the NRC's 10 CFR Part 35, Subpart K guidance(s) are being, or has not yet been, developed and that are of mutual regulatory interest.
NRC and DOE (2023)[163]	Establishing Roles and Responsibilities for National Environmental Policy Act (NEPA) Implementation Requirements for Reactor Demonstration Projects Supported by DOE Addendum No. 7 to the Nuclear Energy Innovation Capabilities Act Memorandum of Understand.
NRC and OSHA (2013)[65]	NRC Responsibilities The NRC is responsible for licensing and regulating the nation's civilian use of byproduct, source and special nuclear materials in order to assure the adequate protection of the public health and safety, promote the common defense and security, and to protect the environment. However, the NRC does not have statutory authority to protect against industrial safety and health hazards that do not involve the use or consequences of licensed radioactive materials. OSHA Responsibilities Under the OSH Act, every employer has a general duty to furnish each employee with employment and a place of employment that is free from recognized hazards that are causing or are likely to cause death or serious physical harm and to comply with all OSHA standards, rules, and regulations (29 U.S.C. 654(a) and 666). In order to minimize workplace hazards, NRC licensees are required to comply with OSHA's standards and regulations. OSHA has authority to regulate employee exposures from all radiation sources not regulated by the NRC. Examples of these radiation sources include x-ray equipment, some accelerators, incidental accelerator-produced radioactive materials, electron microscopes, betatrons, ion implanters, experimental particle physics research colliders (only when used to probe the fundamental properties of nature), and naturally occurring radioactive materials.
NRC and EPA (2002)[164]	For NRC-licensed sites at which NRC determines during the license termination process that there is radioactive ground-water contamination in excess of EPA's MCLs, or for which NRC contemplates either restricted release (10 CFR 20.1403) or the use of alternate criteria for license termination (10 CFR 20.1404), NRC will seek EPA's expertise to assist in NRC's review of a decommissioning or license termination plan. In addition, NRC will consult with EPA if either the planned level of residual radioactive soil concentrations in the proposed action or the actual residual level of radioactive soil concentrations found in the final site survey exceed the radioactive soil concentration in Table 1. With respect to all such sites, the NRC will consult with EPA on the application of the NRC decommissioning requirements and will take such action as the NRC determines to be appropriate based on its consultation with EPA. If the NRC requests EPA's consultation on a decommissioning plan or license termination plan, EPA will provide, within 90 days of NRC's notice to EPA, written notification of its views on the matter.

NRC and FDA (2002)[165]	The purpose of this Memorandum of Understanding (MOU) is to coordinate existing NRC and FDA regulatory programs for (1) medical devices, drugs, and biological products utilizing byproduct, source, or special nuclear material; and (2) the use of potassium iodide (KI) in response to events involving accidental release of radioactive iodine. These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of such products. FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products, i.e., drugs, devices, and biological products. NRC is responsible for licensing and regulating nuclear facilities and material and for conducting research in support of the licensing and regulatory process, as mandated by the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and in accordance with the National Environmental Policy Act of 1969, as amended, and other applicable statutes. NRC responsibilities include protecting public health and safety, protecting the environment, and safeguarding materials in the interest of national security. Upon request, FDA and NRC will assist each other, to the fullest extent possible, in the investigation of incidents or complaints involving products of mutual regulatory concern. Both agencies will make every reasonable effort to accommodate joint inspection or observer requests depending upon availability of personnel and current FDA or NRC priorities. Each agency will assign one or more persons to assure that investigations are coordinated in a manner that maximizes regulatory efficiency and minimizes duplication of effort. Each agency will promptly notify the other when there is a change in an assigned contact person.
OSHA and DOE (1994)[166]	DOE and OSHA will, to the fullest extent possible, cooperate and coordinate at all organizational levels to develop and carry out information exchange, technical and professional assistance, referrals of alleged violations, and related matters concerning compliance and law enforcement activity to ensure the health and well-being of the workforce and the general public. Resolution of policy issues concerning agency jurisdiction and operations will be coordinated by appropriate DOE and OSHA staff with input from the Office of the Solicitor. DOE and OSHA will designate points of contact for carrying out interface activities. The whistleblower protection provisions of the Energy Reorganization Act, 42 U.S.C. Section 5851, as well as those in section 11(c) of the OSH Act, 29 U.S.C. Section 660(c), are applicable to employees of USEC and contractors at USEC administered facilities.
FDA and OSHA (1974)[167]	FDA responsibilities: Prior to the issuance of standards by FDA under the Radiation Control for Health and Safety Act to control the emissions of radiation from electronic products, representatives of FDA will consult representatives of OSHA, during the development stage of the standards, for advice to further assure that the FDA standards will be compatible with OSHA standards relating to radiation or other occupational safety and health hazards. If FDA in its routine compliance program involving an environment has reason to believe that occupational factors are present which may raise questions under the Act, FDA will advise OSHA of its findings. OSHA responsibilities: Prior to the issuance of standards developed under the Act related to radiation from electronic products, representatives of OSHA will consult with FDA during the developmental stage to assure that the radiation safety and health regulations established by OSHA are compatible with the Federal performance standard for electronic product radiation emissions established by FDA. If OSHA in its routine compliance program involving an occupational environment has reason to believe that there are factors present which may indicate a possible violation of FDA standards, OSHA will advise FDA of its findings.

	Shared responsibilities of OSHA and FDA: In States with an approved State plan under Section 18 of the Act, OSHA will encourage State safety and health officials to cooperate with State radiological health officials in the enforcement and the standard setting efforts relating to performance standards for electronic product radiation. Exchange procedures and techniques used in determining compliance with the appropriate regulations promulgated by each agency. Cooperate in the enforcement efforts and thereby avoid duplication of efforts for the purpose of assuring the full safety and health protection of both the employers and the public. Meet on a quarterly basis, or more often as required, to implement and carry out this memorandum.

Appendix VII: State Regulatory Landscape[66,67,71,168]

State	**Agreement State**	**OSHA State Plan****	**Dosage limit**	**Dosimetry requirements**	**PPE requirements (list specifics if documented in reg)**	**Licensure *****	**State Radiation Protection Program or Agency**	**Radioactive Materials Program**
Alabama	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default). Respiratory equipment - NISOH certified.	Yes	Alabama Public Health: Radiation Control	Alabama Public Health: Radiation Control
Alaska	No	State Plan**	NRC standard + 0.5 rem for pregnant women	No state statute - NRC standard applies	No explicit PPE statute (NRC default)	Yes	Alaska Department of Health and Social Services, Division of Public Health: Radiological Health	NRC oversite
Arizona	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default). Respiratory equipment - NISOH certified.	Yes	Arizona Department of Health Services: Bureau of Radiation Control	Arizona Bureau of Radiation Control
Arkansas	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default). Respiratory equipment - NISOH certified.	Yes	Arkansas Department of Health: Radiation Control	Arkansas Department of Health: Radiation Control

California	Yes	State Plan**	NRC standard	No state statute - NRC standard applies	General PPE statute (NRC default or vague language). Respiratory equipment - NISOH certified.	Yes	California Department of Public Health: Division of Radiation Safety and Environmental Management	California Department of Public Health: Radiologic Health Branch
Colorado	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	Require 0.5 mm protection for direct radiation and 0.25 mm protection for scatter radiation. Respiratory equipment - NISOH certified.	Yes	Colorado Department of Public Health and Environment: Radiation Management	Colorado Department of Public Health and Environment: Radioactive Materials Unit
Connecticut	LOI *	State Plan**	OSHA standard + NRC standard (0.5 rem) for pregnant women	NRC standard	Require 0.5 mm protection of lead equivalent for direct radiation and 0.25 mm protection for scatter radiation. Mention of thyroid shields.	Yes	Connecticut Department of Energy and Environmental Protection: Radiation	NRC oversite
Delaware	No	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Respiratory equipment - NISOH certified.	Yes	Delaware Office of Radiation Control	NRC oversite

Florida	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard. Finger or wrist dosimetric devices: shall be worn for analytical x-ray equipment workers and personnel maintaining analytical x-ray equipment.	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Respiratory equipment - NISOH certified.	Yes	Florida Health: Radiation Control	Florida Health: Radioactive Materials
Georgia	Yes	Federal Plan	OSHA standard + NRC standard (0.5 rem) for pregnant women	State statute requiring radiographers - must wear a combination of a direct-reading dosimeter, an alarming ratemeter, and a personal monitoring device. No state statute for other employees -- NRC standard applies	Require at least 0.25 mm lead equivalent material from secondary radiation. Respiratory equipment - NISOH certified.	Yes	Georgia Environmental Protection Division: Radiation Protection Programs	Georgia Environmental Protection Division: Radiation Protection Programs

Hawaii	No	State Plan**		State statute requires radiographers to wear a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD). NRC standard applies	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation.	Yes	Hawaii Indoor and Radiological Health Branch	NRC oversite
Idaho	No	Federal Plan	OSHA standard	OSHA standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation.	Yes	Idaho Department of Health and Welfare: X-ray Licensure	NRC oversite
Illinois	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.25 mm lead equivalent material from secondary radiation. State law defines protective apron as one that is made of radiation attenuating materials, at least 0.25-mm lead equivalent. Respiratory equipment - NISOH certified.	Yes	Illinois Emergency Management Agency: Nuclear and Radiation Safety	Illinois Emergency Management Agency: Radioactive Materials

Indiana	LOI ***	State Plan**	OSHA standard	OSHA standard. Finger or wrist dosimetric devices: required for analytical x-ray equipment workers or personnel maintaining such equipment.	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Respiratory equipment - NVLAP certified.	Yes	Indiana State Department of Health: Medical Radiology Services Program	NRC oversite
Iowa	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Respiratory equipment - NISOH certified.	Yes	Iowa Department of Public Health: Bureau of Radiological Health	Iowa Department of Public Health: Radioactive Materials Program
Kansas	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard State statute requiring radiographers must wear a combination of a direct-reading dosimeter, an alarming ratemeter, and a personal monitoring device.	No explicit PPE statute. (NRC default)	Yes	Kansas Department of Health and Environment: Radiation Control Program	Kansas Department of Health and Environment: Radioactive Materials and Licensing

Kentucky	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No statute delineating when PPE should be used, but there are definitions. Protective apron means an apron made of radiation absorbing materials of at least 0.25 mm lead equivalency and protective barrier means a barrier of radiation absorbing material used to reduce radiation exposure and Protective glove means a glove made of radiation absorbing materials at least 0.25 mm lead equivalent.	Yes	Kentucky Cabinet for Health and Family Services: Radiation Health Branch	Kentucky Cabinet for Health and Family Services: Radioactive Materials Program
Louisiana	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	No state statute. NRC standard will apply	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Mention of lead vests/aprons. Respiratory equipment - NISOH certified.	Yes	Louisiana Department of Environmental Quality: Emergency and Radiological Services Division	Louisiana Department of Environmental Quality: Emergency and Radiological Services Division

Maine	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation.	Yes	Maine Division of Environmental and Community Health: Radiation Control Program	Maine Division of Environmental and Community Health: Radioactive Materials Section
Maryland	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	No state statute. NRC standard will apply	No explicit PPE statute. (NRC default)	Yes	Maryland Department of the Environment: Radiological Health Program	Maryland Department of the Environment: Radioactive Materials Licensing
Massachusetts	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation.	Yes	Massachusetts Radiation Control	Massachusetts Radiation Control: Radioactive Materials Licensing
Michigan	No	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and lead aprons, vests, and gloves mentioned.	Yes	Michigan Occupational Safety & Health Administration : Radiation Safety	NRC oversite
Minnesota	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and thyroid shields mentioned.	Yes	Minnesota Department of Health: Radiation Control	Minnesota Department of Health: Radioactive Materials

Mississippi	Yes	Federal Plan	Annual limit: 5 rem the whole body, the head and trunk, active blood-forming organs, gonads, or lens of eye is; 7.5 rem to hands and forearms, feet and ankles, localized area of skin; and 1.5 rem to other organs. No statute for pregnancy.	Dosimeters should be worn whenever protective clothing or devices are worn	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation.	Yes	Mississippi Division of Radiological Health	Mississippi Division of Radiological Health
Missouri	No	Federal Plan	Combined annual and quarterly limits: 5 rem annual/3 rem quarterly to the while body, head and trunk, major portion of the bone marrow, gonads, or lens of the eye; 30 rem annual/10 rem quarterly to the skin of a large body area; and 75 rem annual/25 rem quarterly to hands, forearms,	Dosimeters required when there is any reasonable possibility of receiving a weekly dose ≤ 50 mrem	No explicit PPE statute (NRC default)	Yes	Missouri Department of Health & Senior Services: Radiation Control	NRC oversite

			feet and ankles. No statute for pregnancy.					
Montana	No	Federal Plan	OSHA standard	OSHA standard	No explicit PPE statute (NRC default)	Yes	Montana Department of Public Health and Human Resources: Radiation Machine Registration	NRC oversite
Nebraska	Yes	Federal Plan	NRC aligned (annual limit: 5 rem (whole body), 15 rem (eye), and 50 rem (skin/extremities)) - 0.5 rem for pregnant women.	NRC standard	Require ≥ 0.5 mm protection of lead equivalent material in high risk settings and mention of lead aprons and thyroid shields.	Yes	Nebraska Department of Health & Human Services: Radiation Control	Nebraska Department of Health and Human Services: Radioactive Materials
Nevada	Yes	State Plan**	NRC aligned (annual limit: 5 rem (whole body), 15 rem (eye), and 50 rem (skin/extremities)) - 0.5 rem for pregnant women.	NRC standard	No explicit PPE statute (NRC default)	Yes	Nevada Radiation Control Program	Nevada Radioactive Material Program

New Hampshire	Yes	Federal Plan	NRC aligned (annual limit: 5 rem (whole body), 15 rem (eye), and 50 rem (skin/extremities)) - 0.5 rem for pregnant women.	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Mention of lead aprons, eyewear, and thyroid shields. Respiratory equipment - NISOH certified.	Yes	New Hampshire Department of Health and Human Services: Radiological Health	New Hampshire Radioactive Materials Program
New Jersey	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	General PPE statute (NRC default or vague language)	Yes	State of New Jersey Department of Environmental Protection: Radioactive Materials Program	State of New Jersey Department of Environmental Protection: Radioactive Materials Program
New Mexico	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	New Mexico Environment Department: Radiation Control Bureau	New Mexico Environment Department: Radioactive Materials
New York	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation and at least 0.25 mm lead equivalent material from secondary radiation. Mention of lead aprons, eyewear, thyroid shields, and other shielding. Respiratory equipment - NISOH certified.	Yes	New York State Department of Health: Radiological Health	New York State Department of Health: Radioactive Materials Licensing

North Carolina	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	General PPE statute (NRC default or vague language)	Yes	North Carolina Radiation Protection Section	North Carolina Radiation Protection Section
North Dakota	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	North Dakota Radiation Control Program	North Dakota Radiation Control Program
Ohio	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	General PPE statute (NRC default or vague language). Mention of shielding requirements for equipment.	Yes	Ohio Department of Health; Radiological Health and Safety	Ohio Department of Health; Radioactive Materials Licensing and Inspection
Oklahoma	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Oklahoma Department of Environmental Quality: Radiation Management	Oklahoma Department of Environmental Quality: Radiation Management
Oregon	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Oregon Radiation Protection Services	Oregon Radioactive Materials Licensing
Pennsylvania	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Pennsylvania Radiation Protection Programs	Pennsylvania Radioactive Materials Licensing Program
Rhode Island	LOI ***	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Rhode Island Department of Health: Radiological Health Program	Rhode Island Department of Health: Radioactive Material
South Carolina	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Radioactive Materials (Title A)	Radioactive Material Licensing and Compliance

South Dakota	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	South Dakota Department of Environment & Natural Resources: Radioactive Materials and Radiation Machines	NRC oversite
Tennessee	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	General PPE statute (NRC default or vague language)	Yes	Tennessee Department of Environment & Conservation: Radiation	Tennessee Radioactive Material and X-Ray Permits
Texas	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	Require at least 0.5 mm protection of lead equivalent material from direct radiation. Mention of lead aprons, eyewear, thyroid shields, and other shielding.	Yes	Texas Department of Health Services: Radiation Control Program	Texas Department of Health Services: Radiation Control Program
Utah	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Utah Division of Waste Management and Radiation Control	Utah Radioactive Materials Regulatory Program
Vermont	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Vermont Health and the Environment: Radiological Health	Vermont Radioactive Materials Program
Virginia	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Virginia Department of Health: Radiological Health	Virginia Department of Health Radioactive Materials Program
Washington	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Washington State Department of Health: Radiation Protection	Washington State Department of Health: Radioactive Materials
West Virginia	LOI ***	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	West Virginia Radiological Health Program	NRC oversite

Wisconsin	Yes	Federal Plan	NRC standard + 0.5 rem for pregnant women	NRC standard	General PPE statute (NRC default or vague language)	Yes	Wisconsin Department of Health Services: Radiation Protection	Wisconsin Department of Health Services: Radioactive Materials Program
Wyoming	Yes	State Plan**	NRC standard + 0.5 rem for pregnant women	NRC standard	No explicit PPE statute (NRC default)	Yes	Wyoming Homeland Security: Radiological Services	Wyoming Homeland Security: Radiological Services

** Letter of Intent (LOI) state.*
*** State Plan includes private workers in addition to state and local government workers*
**** Licensure required for radiation oncologists and medical physicists*
Dose:
NRC Standard - Annual limit of 15 rem to lens of the eye & 50 rem to skin/extremities
OSHA Standard - Quarterly limit: 1.25 rem to whole body (head and trunk; active blood-forming organs; lens of eyes; or gonads); 18.75 rem to hands forearms and ankles; and 7.5 rem to skin of whole body.
Dosimetry:
NRC Standard - Dosimeter required for: adults likely to receive ≤ 10% and minors likely to receive a deep dose ≤ 0.1 rem, a lens dose ≤ 0.15 rem, or a shallow dose ≤ 0.5 rem
OSHA Standard - Dosimeter required for individuals likely to receive an annual dose ≤ 25% of the limit; minors where they'll likely receive ≤ 5% of their limit quarterly.

Appendix VIII: Existing AMA policy on radiation

H-455.994 Risks of Nuclear Energy and Low-Level Ionizing Radiation

1. Our American Medical Association supports the following policy on nuclear energy and low-level ionizing radiation. Usefulness of Nuclear Energy: Energy produced by nuclear reactors makes an important contribution to the generation of electricity in the US at present, and it will continue to do so in the foreseeable future. Investigation and research should continue in order to develop improved safety and efficiency of nuclear reactors, and to explore the potential of competing methods for generating electricity. The research should include attention to occupational and public health hazards as well as to the environmental problems of waste disposal and atmospheric pollution.
2. Research on Health Effects of Low Level Radiation: There should be a continuing emphasis on research that is capable of determining more precisely the health effects of low level ionizing radiation.
3. Uranium Mill Tailings: Uranium mill tailings should be buried or otherwise covered.
4. Radioactive Waste Disposal: There should be acceleration of pilot projects to evaluate techniques for the disposal of high-level radioactive wastes. The decommissioning of nuclear reactors is a source of nuclear waste which requires accelerated technological investigation and planning.
5. Occupational Safety: The philosophy of maintaining exposures of workers at levels "as low as reasonably achievable (ALARA)" is commended. The present federal standards for occupational exposure to ionizing radiation are adequate. The responsibilities of the various federal agencies regarding workers in the nuclear energy industry should be clarified; these agencies include the Departments of Energy, Defense, HHS, Labor and Transportation; and the NRC, VA and EPA.
6. Minimizing Exposures to Radiation: Each physician should attempt to minimize exposures of patients to ionizing radiation in accord with good medical practice.
7. Radiation Exposure Standards: The present standards for exposure of populations to ionizing radiation are adequate for the protection of the public.
8. Emergencies and Governmental Readiness: Government agencies at all levels should be prepared to respond to nuclear energy-related emergencies. There is need for improved public planning by the several federal agencies involved, including the Federal Emergency Management Agency (FEMA) and the agencies of state and local governments. Responsible officials should develop skills and undergo periodic retraining in order to be able to act appropriately during major radiation emergencies. Because emergency planning is a complex task involving

aspects of health as well as problems related to utilities, state and local governments and the federal government (FEMA) would benefit from the cooperation of physicians and others in the health sciences.

9. Federal Radiation Emergency Planning Responsibilities: Federal groups such as the NRC and FEMA must work together closely to fulfill responsibilities in radiological emergency preparedness and in crisis management. There is a need for NRC and FEMA to define better the roles of community hospitals and of physicians.
10. Reactor Operators and Radiation Inspectors: There is a need for better training of operating personnel with regard to prevention and management of untoward reactor operating conditions. Selection, training, and ongoing performance evaluation of operating personnel, and of radiation inspectors, are key elements in the safety of reactor workers and of the public. Physicians should help develop methods of selecting and evaluating personnel in the nuclear power industry.
11. Radiation Training for Physicians: Physicians should be prepared to answer the questions of their patients about ionizing radiation, especially if there is a radiation emergency. Each hospital should have adequately trained physicians and a plan and protocol for receiving and caring for radiation victims.
12. Radiation Education for the Public: Further education of the public about ionizing radiation is recommended.
13. Location of Nuclear Reactors: All nuclear reactors built in the future should be placed in areas of low population density; present reactors located in low density areas should be managed so that the populations surrounding them remain small.
14. Multiple Sources of Power Generation: AMA recommends the use of a diverse set of electricity generating methods and a continuing emphasis on the conservation of energy.
15. X-Ray Security Scanners:
    1. Our AMA believes that as of June 2013, no data exist to suggest that individuals, including those who are especially sensitive to ionizing radiation, should avoid backscatter security scanners due to associated health risks.
    2. Our AMA supports the adoption of routine inspection, maintenance, calibration, survey, and officer training procedures meant to ensure that backscatter security scanners operate as intended.
16. Our AMA supports continued authorization of federal radiation exposure compensation programs and expanded program eligibility to downwind individuals, communities, and tribes affected by the ongoing environmental harms of historic atomic weapons testing, including, but not limited to, residents of areas affected by the test of the first atomic bomb in New Mexico and uranium miners employed between 1942 through 1990. [CSA Rep. A, A-81Reaffirmed: CLRPD Rep. F, I-91Reaffirmed: Sunset Report, I-01Reaffirmed: CSAPH Rep. 1, A-11Appended: CSAPH Rep. 4, A-13Modified: CSAPH Rep. 8, A-23Modified: Res. 435, A-24]

H-455.976 Monitoring Patient Exposure to Ionizing Radiation

Our American Medical Association will support public health, radiology and radiation oncology specialty societies and all other interested parties to monitor the issue of radiation exposure to the American public and develop a plan, if appropriate, to allow the ongoing monitoring and quantification of radiation exposure sustained by individual patients in medical settings. [CSAPH Rep. 8, A-23]

H-455.975 Regulation of Ionizing Radiation Exposure for Health Care Workers

Our American Medical Association encourages public and private healthcare institutions to ensure comprehensive coverage of different body types by providing readily available PPE that reduces exposure to as low as reasonably achievable for employees of all genders and pregnancy statuses.

Our AMA will work with the appropriate and interested parties to study how best to accomplish comprehensive protection from ionizing radiation for employees, taking into account variation in body types, pregnancy status, specifics of procedures being performed, as well as how exposure can be limited beyond PPE (personal protected equipment), with report back at I-25. [Res. 904, I-24]

H-455.977 Ionizing Radiation Exposure in the Medical Setting

1. Our American Medical Association will support appropriate specialty medical societies and other interested stakeholders to collaborate:
    a. For feasibility of monitoring and quantifying the cumulative radiation exposure sustained by individual patients in medical settings.
    b. Continue to educate physicians and the public on the appropriate use and risks of low linear energy transfer radiation in order to reduce unnecessary patient exposure in the medical setting.
2. Our AMA will continue to monitor the National Academy of Sciences' ongoing efforts to study the impact of low levels of low linear energy transfer radiation on human health.

3. Our AMA will support education and standards for all providers and medical personnel using ionizing and non-ionizing radiation that includes awareness of, and methods to avoid, patient over-radiation.
4. Our AMA will support policies that promote the safe use of medical imaging devices, informed clinical decision-making regarding the use of procedures that use radiation, and patient awareness of medical radiation exposure.
5. Our AMA will encourage the continued development and use of standardized electronic medical record systems that will help physicians track the number of imaging procedures a patient is receiving, in both the in-patient and out-patient settings, which will help physicians discuss the potential dangers of high level of radiation exposure with patients. [CSAPH Rep. 8, A-23].

H-455.996 Nuclear Regulatory Commission Licensure Requirements for Physicians
Our AMA urges the U.S. Nuclear Regulatory Commission to continue to require that the training requisite for licensure be documented, and that it contain elements of instruction in radiological physics, radiation biology, radiation safety, nuclear instrumentation, and the safe and effective clinical use of radionuclides in patients. [Res. 148, A-80Reaffirmed: CLRPD Rep. B, I-90Modified: Sunset Report, I-00Reaffirmed: CSAPH Rep. 1, A-10Reaffirmed: CSAPH Rep. 01, A-20]

H-455.978 Nuclear Regulatory Commission Medical Use Program
The AMA encourages the efforts of the Nuclear Regulatory Commission to assure that any regulations that affect the practice of nuclear medicine and radiology be science-based. [Sub. Res. 516, I-97Reaffirmed: CSAPH Rep. 3, A-07Reaffirmed: CSAPH Rep. 01, A-17]

D-455.993 Interference with Practice of Medicine by the Nuclear Regulatory Commission
Our AMA will express its opposition to the imminent proposed changes to the Section 10 CFR Part 35.390(b) by the Nuclear Regulatory Commission (NRC) which would weaken the requirements for Authorized Users of Radiopharmaceuticals (AUs), including shortening the training and experience requirements, the use of alternative pathways for AUs, and expanding the use of non-physicians, with AMA advocacy for such opposition during the open comment period ending July 3, 2019. [Res. 719, A-19]

H-135.985 Environmental Protection and Safety in Federal Facilities
The AMA urges physicians to contribute to the solution of environmental problems by serving as knowledgeable and concerned consultants to environmental, radiation, and public health protection agencies of state and local governments. [BOT Rep. T, I-87Reaffirmed: Sunset Report, I-97Reaffirmed: CSAPH Rep. 3, A-07Reaffirmed: CSAPH Rep. 01, A-17]

H-455.988 Public Education on the Danger of Radiation Exposure
Our American Medical Association supports public initiatives, such as the "Image Wisely" and "Image Gently" campaigns, which aim to increase awareness of radiation in the medical setting and reduce exposure. [Res. 121, A-86Reaffirmed: Sunset Report, I-96Reaffirmed: CSAPH Rep. 3, A-06Appended: Res. 921, I-11Modified: CSAPH Rep. 1, A-21]

H-455.993 Treatment of Radiation Accident Victims
1. Our American Medical Association encourages all acute care facilities, through their medical staffs, to review and become familiar with radiation accident contingency plans required by the JCAHO, particularly those facilities in areas where major radiation-emitting equipment is located.
2. Our AMA supports the development of guidelines for training and preparedness of medical staffs, proper treatment regimens and the maintenance and use of decontamination equipment for use at the time of radiation accidents. [Res. 36, I-81Reaffirmed: CLRPD Rep. F, I-91Reaffirmed: Sunset Report, I-01Reaffirmed: CSAPH Rep. 1, A-11Reaffirmed: CSAPH Rep. 1, A-21]

H-460.938 Effects of Electric and Magnetic Fields
Our American Medical Association will continue to monitor developments and issues related to the effects of electric and magnetic fields, even though no scientifically documented health risk has been associated with the usually occurring levels of electromagnetic fields.
Our AMA encourages research efforts sponsored by agencies such as the National Institutes of Health, U.S. Department of Energy, and the National Science Foundation to continue on exposures to

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3. PLASTIC POLLUTION REDUCTION

Reference committee hearing: see report of Reference Committee K.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy D-135.976 and H-135.901

AMA Policy H-135.901, "Addressing the Health Consequences of Microplastics in Humans," was adopted by the House of Delegates (HOD) at the 2025 Annual Meeting and asks the following:

1. Our AMA recognizes the potential health risks associated with microplastics exposure and encourage increased research to better understand the human health effects of microplastics.
2. Our AMA supports the respective specialty medical societies with subject matter expertise and federal and state public health agencies, including the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA), to develop evidence-based guidelines for monitoring and mitigating microplastic exposure in water, food, air, and other consumer products.
3. Our AMA will collaborate with relevant stakeholders to promote public education about microplastics, their sources, potential health risks, and possible strategies for reducing exposure.
4. Our AMA will study and report back with policy recommendations on ways to reduce plastic pollution and its impact on climate change and health, including but not limited to federal, state, and local taxes and limitations on the use of single-use plastic consumer products and other types of plastic, interventions to reduce microplastics, and alternatives to plastic. [Res. 429, A-25, Res. 418, A-25][1]

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases using the search terms "plastics" AND "health", "microplastics" AND "health," "plastics" AND "climate change," and "bioplastics" and "plastic waste management." A 2023 report by the Minderoo-Monaco Commission on Plastics and Human Health, an international and interdisciplinary group comprised of scientists, healthcare workers, and policy analysts, served as a primary reference for this report, as it synthesized and summarized health impacts from plastic across its life cycle, and included over 1500 references. Legal research tools, state legislative databases, and municipal websites were also searched to identify which jurisdictions have passed legislation on limiting plastic, supported by keyword combinations like "microbead ban," "plastic bag tax," and "single-use container legislation." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and advocacy organizations were also reviewed for relevant information. Due to the technical nature of this report, a glossary of terms is provided at the end in Appendix A for easy reference.

DISCUSSION

Plastic is a component in a wide array of everyday products. Plastic production has increased exponentially, particularly in the last two decades with the growth in the production and use of single-use plastics.[2] With this large growth in plastics, the associated waste has also grown, and plastic has increasingly come under scrutiny in terms of its negative environmental and health impacts. Only a small percentage of plastic is currently recycled, meaning most of it ends up in landfills or in the environment, such as in rivers, lakes or the ocean.[2] In this way, plastics have become pervasive and ubiquitous in our natural and built environments across the globe. There is also concern that as plastic degrades and breaks down, smaller plastic particles, otherwise known as microplastics, end up inside animals and humans alike, which is associated with its own negative impacts.[3] This report provides a brief summary of plastic production as well as the known health and environmental impacts from plastic, looking across the product lifespan. The report also addresses interventions and strategies to reduce plastic and plastic-related pollution and thereby reduce harm to human health and the environment.

What is plastic and what are microplastics?

Plastic is an important component in a diverse range of products, many of which are crucial and, in some cases, lifesaving in our modern society. Plastics are ubiquitous in products within medicine, electronics, aerospace,

construction, food packaging, and synthetic clothing, just to name a few. Its use in a wide variety of products is tied to its chemical structure and its relatively inexpensive production cost.[4] While there are many types of materials that are considered plastic, it is generally defined as a synthetic or semi-synthetic material that uses carbon-based polymers as its primary ingredient.[4] A polymer is a large molecule that is made up of many repeating, smaller units (or monomers), arranged in a chain-like or network-like chemical structure.[5] In the case of most synthetic plastics, the polymer chain is composed of carbon atoms found in a repeating pattern, often with side branches. Due to their chemical nature, plastic polymers are both very flexible and very durable. Plastics' flexibility allows them to be molded into many different forms, which is helpful from a product perspective. However, its durability is a major factor in their impact on our environment and health, in that they do not easily break down chemically.[6] Nearly 98 percent of synthetic plastic polymers are derived from fossil fuels, such as ethane, propane, and methane, through an industrial process called cracking.[4] Depending on the plastic fossil-fuel base, different industrial cracking processes are employed to create various plastic polymers.[4] A few examples of plastic polymers include polypropylene and polyethylene, with polyethylene being the most widely used plastic in the world.[7]

Following cracking, the manufacturing process to make a finished plastic product involves adding chemicals to the plastic polymer, which are used as both processing aids and additives. Processing aids are employed to improve efficiency and quality while additives provide a wide range of functional and aesthetic properties.[4,8] There are over 10,500 chemicals known to be used in the plastic manufacturing process, a majority of them additives for which there is little understanding of their overall safety and health impacts.[9] A few well-known and better studied additives include phthalates, bisphenols, brominated chemicals, and perfluoroalkyl and polyfluoroalkyl chemicals, also known as PFAS chemicals.[10] Phthalates are used in plastics to increase their flexibility, transparency, durability, and longevity.[11] Bisphenols make plastic hard and clear and are used as a protective coating on the inside of food and beverage cans.[11] Brominated chemicals are one class of chemicals that help reduce product flammability.[11] Lastly, PFAS chemicals are a common component in many plastic consumer products, such as food packaging, clothing, and cosmetics, as they help create grease-resistant and water-resistant surfaces.[10]

In 1950, global plastic production was less than two million tons and in 2019 it was 460 million tons (see Figure 1).[2] Plastic production is anticipated to triple by 2060.[4] There has been massive investment in fossil fuel-based plastic production by major, multinational energy companies to create alternative revenue streams for products derived from fossil fuels, partly in response to growing demands for renewable energy.[4] Supplies of inexpensive natural gas, made possible through the expansion of shale fracking in the U.S., has also been fueling new investments in plastic manufacturing infrastructure in the U.S. and abroad.[12] Increased plastic production investment is notable in the U.S., China, Middle East, and Europe.[4] Single use plastics are a major driver of increased plastic production.[13] Single-use plastics are plastic items designed to be used once and then disposed of, as opposed to being reused or recycled. These include food packaging and containers, plastic bags, plastic straws, face masks, medical gloves, etc. The health care industry is a large user of single-use plastics and a contributor to plastic waste.[14] Nearly a quarter of the 14,000 tons of waste generated daily in U.S. health care facilities is plastic.[15]

Challenges with plastic waste disposal have become increasingly problematic as global production has grown. While recycling strategies are effective for other materials such as paper, glass and aluminum, only a small percentage of plastic is currently recycled (around nine percent globally and only about five percent in the U.S.).[2,4] To provide a point of comparison, about 68 percent of paper and paperboard, 25 percent of glass, and about 35 percent of aluminum containers and packaging is recycled in the U.S. (as of 2018).[16,17] If not recycled, disposal strategies for plastic include controlled or uncontrolled landfilling, open burning, thermal conversion, or export.[4] Large quantities of plastic are exported from high-income to low-income countries where it is landfilled.[18] It is estimated that somewhere between 75 to 80 percent of plastic is landfilled or is improperly discarded into the natural environment where it will persist for hundreds to thousands of years.[4,19] Additionally, around 14 percent is incinerated, which is associated with a number of environmental and health downsides, and some plastic is converted to energy in waste-to-energy facilities.[4] As plastics degrade in landfills and within the environment, they break down into smaller and smaller pieces, often referred to as microplastics. Microplastics are pieces of plastic that range in size but are defined as less than 5 millimeters, while nanoplastics are smaller than 1 micrometer.[20]

Impacts of plastic on the environment and human health

Plastics have negative repercussions on both the environment and human health at every stage of their lifecycle, from extraction through production, to use and disposal (see Figure 2). The following is not an exhaustive summary of all

potential negative environmental and health impacts from plastics but is intended to provide a broad snapshot of impacts across the plastic life span. The Minderoo – Monaco Commission on Plastics and Human Health report includes a comprehensive analysis of plastic's health impacts across its lifecycle and is a useful resource for an-depth look at this issue.[4]

Extraction and Production Phases

During the extraction of fossil fuels and production of plastics, there are numerous environmental harms, occupational risks, and increased exposure to dangerous chemicals and pollutants for nearby communities. Since plastic is primarily derived from fossil fuels, individuals who work in the oil and gas industries are most affected and face severe occupational health risks and disparities in health outcomes. Workers in the fossil fuel industry have higher rates of other negative health outcomes due to increased exposure to dangerous chemicals, such as increased mortality from cardiovascular disease and several types of cancer, including mesothelioma.[21] Workers in fossil fuel industries also face substantial safety hazards, including but not limited to explosions and fires due to the ignition of flammable vapors or gases, falls from platforms or equipment, and transportation issues. Highway vehicle crashes are the leading cause of death among oil and gas extraction worker fatalities.[22]

Oil spills also pose significant environmental and human health harms. The U.S. National Oceanic and Atmospheric Administration reports that oil spills are relatively common, with thousands occurring each year, most of them small.[23] However, when large oil spills occur, they can be major disasters and especially dangerous, such as the Exxon Valdez spill in 1989 or the Deepwater Horizon spill in 2010. Whether large or small, oil spills can have damaging effects, such as releasing toxic chemicals into the environment and covering local wildlife in oil, which can put them at physical risk.[23] The Deepwater Horizon oil spill is a useful case study for understanding the many public health impacts from oil spills. Clean-up workers experienced respiratory issues, skin rashes, headaches, and nausea.[24] Local communities impacted by the spill reported increased stress, anxiety, and depression, as well as economic hardship that was largely due to concerns about the safety of seafood and a decrease in tourism to the area, threatening their livelihoods.[24,25]

Early signs that plastics could cause health harm came from occupational settings in the 1970s. Workers in plastic manufacturing had elevated risks of angiosarcoma of the liver from working with vinyl chloride (a gas that is used primarily to make polyvinyl chloride, a hard plastic resin) as well as dermatitis and respiratory ailments from exposure to other chemicals used in the process.[26,27] Thousands of chemicals are used in plastic production and at least one third of the known chemicals have a high or medium concern as a human health hazard.[4] Workers within plastic manufacturing are exposed to chemicals at much higher levels than the general public, primarily through inhalation.[27]

Depending on the type of fossil fuel, populations living near extraction and production facilities may be at higher risk of adverse health outcomes. Fracking, for example, has been shown to contaminate surrounding water sources, create noise and air pollution, and trigger earthquakes.[28,29] Children living near fracking sites in Pennsylvania around their birth were two to three times more likely to be diagnosed with leukemia between the ages of two and seven than those who were not exposed to fracking at a young age.[29] Pregnant mothers living close to fracking sites in Pennsylvania had an increased risk of giving birth prematurely and of having high-risk pregnancies.[29] A recent study also found that pregnant women who live in counties with higher levels of fracking activities in Texas were at much higher risk of giving birth to children with specific birth defects.[30] Fracking sites are also disproportionately located in areas of poverty and minority communities.[28]

Use and Disposal Phases

During its use phase, there are potential health risks from microplastics degrading from the plastic product as well as the thousands of chemical additives in plastic. Humans are exposed to micro- and nano- plastics through food, water, and air.[3] Microplastics have been found throughout human tissues and bodily fluids, including the lungs, colon, spleen, kidneys, liver, heart, placenta, blood, great vessels, meconium, feces, and breastmilk.[3,31,32] Recent studies have also identified microplastics in the brain, indicating there is possibility of microplastics passing through the blood-brain barrier.[33,34] There are many factors that influence the potential toxicity of microplastics, including size, shape, and chemical properties. The potential physiological mechanisms for impact are complex, but include oxidative stress, neurotoxicity, metabolic dysfunction, and induction of immune responses within the body.[3] While research on the health impacts of microplastics in our body is still nascent, recent research found a four-fold increase in the risk of poor cardiovascular outcomes in patients with microplastics present in their carotid artery plaque.[35] The presence of microplastics in our bodies has also been associated with respiratory complications, endocrine disruption,

inflammatory bowel disease symptom severity, narrowing of fetal capillaries, and stomach and esophageal cancers, although the biological mechanisms for these effects are not entirely clear at this time.[36]

Microplastics can also be viewed as “trojan horses” as they carry with them a complex array of chemicals which separate from the plastic and spread throughout our bodies via the circulatory system.[3] While health and safety information are lacking for most chemicals in plastic, at least four major categories of chemicals found in plastics have been more extensively studied in terms of health impacts. These include phthalates, bisphenols, PFAS, and flame-retardant additives.[11] The effects of these chemical additives are known to affect nearly every organ system in the body of people of all ages, but particularly young children.[9]

A meta-analysis on human health impacts from several major classes of plastic-associated chemicals found they are associated with adverse health outcomes across a wide range of human health conditions.[10] Bisphenol A (BPA) is classified as an endocrine disrupting chemical and is associated with decreased anoclitoral distance in infants (an indicator of potential reproductive health issues later in life), type 2 diabetes in adults, insulin resistance in children and adults, polycystic ovary syndrome, obesity and hypertension in children and adults, and cardiovascular disease.[10,37] As public awareness of BPA has increased, manufacturers have switched to alternative bisphenol formulations, which have very similar chemical structures, and thus may have similar health effects but have yet to be studied.[11]

Phthalates, commonly used as plasticizers to make plastic more flexible and durable, are also well-known endocrine disruptors and impact reproductive systems.[38] Phthalates are associated with spontaneous pregnancy loss, decreased anogenital distance in boys, insulin resistance in children and adults, with additional associations between certain phthalates and decreased birth weight, type two diabetes in adults, precocious puberty in girls, reduced sperm quality, endometriosis, adverse cognitive development and intelligence quotient (IQ) loss, adverse fine motor and psychomotor development and elevated blood pressure in children and asthma in children and adults.[10] Some phthalates were removed from the market in Europe in the 1990s due to health concerns and various substitutes have been introduced but there are few studies assessing their health impacts.[11]

Polychlorinated biphenyls (PCBs) and polybrominated diphenyl ethers (PBDEs) are utilized as flame retardants in plastics. PCBs and PBDEs are associated with decreased birth weight and in general populations, PCBs are associated with type 2 diabetes in adults and endometriosis, bronchitis in infants, cardiovascular disease, non-Hodgkin's lymphoma and breast cancer.[10] In PCB-poisoned populations, exposure is associated with overall mortality, mortality from hepatic disease (men), cardiovascular disease in both men and women, and several cancers. PBDEs are adversely associated with children's cognitive development and IQ loss as well as changes in thyroid function.[11]

Lastly, PFAS exposure is associated with decreased birth weight, increased body mass index and overweight in children, attention deficit hyperactive disorder in girls, and allergic rhinitis.[10] Some PFAS have also been associated with changes in thyroid function.[10] Notably, PFAS chemicals have been found in measurable amounts in the blood of nearly all Americans based on data from the National Health and Nutrition Examination Survey since the late 1990s.[39] Recent estimates on the economic costs of health impacts from the chemicals in plastic demonstrate that U.S. health costs are around $249 billion in plastic-attributable disease burden in 2018, which are likely an underestimation due to limitations on not knowing the full extent of chemical exposure in the population.[40]

Once disposed of poor waste management contributes to plastic and microplastics accumulating in both soil systems and water environments. Plastic particles have been identified in environments across the globe, from Antarctica to the Arctic, in the peaks of the Himalayas to the deepest trenches of the ocean.[3] Plastic pollution is considered a planetary boundary threat (a term used to describe global change processes where human activities affect Earth system functioning in a substantial way) and is having negative effects on Earth ecosystems by contributing directly to climate change and negatively impacting biodiversity loss.[41,42] Microplastics within the soil can facilitate the proliferation of biological disease factors and impact water filtration and soil aeration, which may impact plant growth and productivity.[19] Additionally, the presence of microplastics has been detected in 1300 terrestrial and aquatic species from across the entire food chain web.[43] Plastic waste also accumulates in bodies of water, with some researchers estimating that a garbage truck’s worth of plastic enters the ocean every minute.[18] In water environments, plastic pollution is an increasingly visible and pervasive problem, as best evidenced by the Great Pacific Garbage Patch, an area that due to ocean currents has brought together a large concentration of trash, primarily plastics.[44] While it is difficult to estimate its size with certainty, as it is constantly in motion, some studies have estimated that the Great Pacific Garbage Patch covers an area roughly twice the size of Texas.[45] Within the water, various organisms interact

with plastics and microplastics, either ingesting it or getting entangled, which has resulted in more than 400,000 documented marine animal deaths.[46]

The health challenges of plastic waste disposal are not limited to microplastics in the soil and water. With nearly two billion people across the globe lacking solid waste collection services and plastic waste routinely being shipped from higher income countries to low- and middle-income countries under the guise of recycling, plastic waste is often incinerated in open burning pits, which is a primary method of disposal in many parts of the world.[47–49] The amount of plastic being burned is estimated to be roughly equivalent to the quantity entering the sea or soil.[47] Incineration of plastic waste is a major source of air pollution that contains many toxic substances including brominated compounds, dioxins, mercury, and black carbon, to name just a few.[48,50] Many of these compounds are known carcinogens, cause reproductive and development problems, increase the risk of heart disease, and aggravate respiratory disease, such as asthma and emphysema.[48,50]

Relationship between plastic and climate change

Plastic also contributes to greenhouse gas emissions (GHG) along the entirety of its life cycle and accounts for approximately four percent of all global GHG emissions (See Figure 3 in Appendix B).[4,51] Since plastic polymers are primarily derived from fossil fuels and the process of cracking is energy intensive, the production and manufacture of plastics account for a majority of the known GHG emissions over the plastic lifespan. Additionally, the end-of-life processes for plastic waste – which could be incineration or shipping from high-income countries to low and middle-income countries – also contributes to GHG emissions.[51]

There is increasing evidence that anthropogenic increases in GHG emissions in the last 150 years are increasing global surface temperatures which is impacting climate patterns.[52,53] These changes are causing regional and seasonal temperature extremes, reducing snow cover and sea ice, and intensifying heavy rainfall. Climate change has already caused irreversible damage. The consequences of unmanaged climate change include droughts, water scarcity, rising sea levels and flooding, severe fires, melting polar ice, temperature extremes, declining biodiversity, increased vector-borne diseases, and catastrophic storms, all of which impact health and safety.[54] For more details on how climate change impacts health, refer to previous AMA Council on Science and Public Health reports from 2022 and 2008, or view the AMA report, *Addressing the Public Health Crisis of Climate Change*.[54–56]

STRATEGIES FOR REDUCING PLASTIC POLLUTION AND REDUCING HARM

Due to the overwhelming quantities of plastic being produced and the scale of the problem, meaningful action to reduce plastic pollution globally should focus on reducing the amount of plastic being produced in the first place through upstream policy and economic levers, as opposed to relying on individual behavior change. The Minderoo-Monaco report includes several recommendations for reducing plastic pollution, the primary one being the passage of a UN Global Plastics Treaty, which is in the process of being developed and debated.[4] One of the key components of this treaty would aim to create a global cap on plastic production. As of April 2024, the European Union approved new rules to reduce, reuse and recycle packaging, with certain single-use plastic packaging types banned as of 2030.[57] The types of packaging that will be banned include packaging for unprocessed fresh fruit and vegetables, for foods and beverages filled and consumed in cafés and restaurants, individual portions (e.g., condiments, sauces, creamer, sugar), miniature toiletry products, and very lightweight plastic carrier bags.[57] A summary of U.S.-based legislation on plastics and single-use plastic bans is provided in a subsequent section. Additionally, as opposed to a linear use framework (production → use → disposal), it has been suggested that the modern plastic economy needs to be converted to a more sustainable, circular model. This requires a shift to an integrated waste management framework focused on the hierarchy of 'reduce, reuse, recycle, and recover,' which would help reduce the overwhelming strain of plastic pollution.[19,41]

Improved waste management

Recycling is an important strategy for addressing plastic waste. However, as the low recycling rate of plastic indicates, there are many barriers to making plastic recycling a more viable option. Challenges include the chemical diversity of plastic products, contamination of the plastic during collection, inadequate infrastructure, unknown toxins, and the downcycling of recycled plastics, all of which hinder the effectiveness and efficiency of plastic recycling processes.[58–60] As there are many types of plastic produced, with many containing multiple materials with other non-recyclable

materials or complex structures and many used for food storage, there can be numerous contaminants with the plastic waste stream making it difficult to separate and process the plastic effectively.[58] The U.S. also has outdated and inadequate recycling infrastructure and collection systems to keep pace and efficiently manage plastic waste streams. Inadequate infrastructure coupled with a lack of consumer education and understanding on what materials can be recycled and how has led to very poor recycling rates in the U.S. and therefore leads to plastic accumulation in landfills and the environment.[58]

The regulatory and economic environment around waste management in the U.S. is also an important contributing factor. Recycling rates in Europe are on average considerably higher than the U.S. In 2021 the European Union achieved a 32.5 percent recycling rate for plastic waste, while a few countries were closer to the 50 percent recycling rate target that has been set (Germany and the Netherlands recycled 36 percent and 47 percent, respectively).[61] A contributing factor to this difference is the associated costs of end-of-life disposal methods, with most European Union citizens paying higher prices for both landfilling and incineration, which helps make recycling a more favorable option. As a result, this has led to more industrial processing and innovation, more recycled product uptake, and the structuring of collection and sorting methods that help reduce cross-contamination which makes recycling more efficient.[61] Additionally, the U.S. operates under a patchwork of state and local regulations when it comes to recycling as there is no overarching federal law on recycling.[62]

Another challenge with plastic recycling is that most of these processes result in "downcycling," where the recycled plastic is used to make lower-quality products compared to the original material and therefore even recycled plastics can only go through one or two recycling cycles before being unable to be used again versus glass or metal products which can go through several iterations of recycling (glass can be recycled an infinite number of times as its properties do not degrade over time).[59] Additionally, since various plastics could potentially contain thousands of different chemicals, recycling processes may increase the toxicity of the plastics due to the introduction of new chemicals or increase the concentration of existing ones.[59] Plastic recycling processes may also release microplastic pollution in the environment.[63] Lastly, the cost of collecting, sorting, and processing plastic waste can be high, and the domestic market demand for recycled plastic has not been sufficient to support a robust plastic recycling market.[58]

There are several potential solutions to address the challenges with plastic recycling, which include the promotion of innovative, circular design concepts with plastic products, technological and infrastructure improvements, consumer education, and creating market incentives for recycled products. Prior to production, better and innovative design that considers the entire life cycle of plastic, with recycling in mind, could aim to use fewer materials and make it easier to separate components, thus improving recyclability.[41] Recycling infrastructure investment is also seriously needed in the U.S. Expanding and modernizing recycling facilities and collection systems is critical for managing the growing amount of plastic waste effectively.[58] To reduce microplastic pollution and other potential pollutants while recycling, additional environmental filtration controls are recommended to decrease the volume of air pollution and microplastics entering water systems.[63] These types of investment would also need to be coupled with the development of more advanced sorting systems to help separate different types of plastics more effectively for processing.[41,58] On the consumer side, better education on proper recycling practices and the importance of reducing plastic consumption can help reduce contamination and increase participation, which could also help create consumer demand for recycled plastic products.[58] Education coupled with incentives for recycling and recycled products could potentially help make recycled plastic more economically viable over the long term.

Reformulation and alternatives

As concerns over plastic have grown, so has interest in finding alternatives, such as bioplastics. Bioplastics are generally described as plastics made from non-fossil fuel,[1] renewable polymers derived from starches and proteins and break down via natural processes (i.e., they are biodegradable).[64,65] Currently, bioplastics account for roughly one percent of the overall global plastics market.[19,66] There are several advantages to bioplastics, including their ability to save fossil fuel resources, reduce greenhouse gas emissions, and improved end of life outcomes if they are compatible with existing recycling systems and biodegrade.[19,67]

[1] There are a few biodegradable fossil-fuel derived plastic polymers that can be categorized as a bioplastic. However, the majority are not and therefore the focus of this section is on renewable sources of bioplastic polymers from natural sources.

However, the ability for bioplastics to become a more substantial alternative to synthetic plastics in the market over the medium or even long-term is unrealistic due to several factors. First, large scale production of bioplastics is more expensive compared to synthetic plastics derived from fossil oils, partially as a result of the increased supply of inexpensive natural gas, and therefore not economically viable currently.[68] Bioplastics are also not up to par on certain physical and chemical properties as compared to synthetic plastics, and exhibit poor functional quality due to high-water vapor permeability, oxygen permeability, fragility, low thermal resistance, low mechanical properties, vulnerability to degradation, and low processability.[68] Another challenge with bioplastics is that their production, which comes from agricultural products such as corn, competes with food production for consumption and increased production would require the use of arable land, fertilizers, and pesticides for crops, which can also have negative environmental repercussions, such as soil erosion and degradation.[19,67] There are also concerns that while bioplastics are "biodegradable," it is not well understood how they will adequately break down in open environments or outside of industrial composting facilities.[19] Lastly, bioplastics are also produced with the use of chemical additives to provide specific physical properties and therefore may pose a similar risk as some of the chemicals used in synthetic plastics without improved understanding of those chemicals and potential health harms.[19] While the market for bioplastics is expected to grow, there are still challenges that need to be overcome for bioplastics to occupy a larger share of the plastics market and contribute meaningfully to the reduction in plastic waste and pollution.

Health Care Strategies

Recommendations for reducing plastic waste in the health care sector include: increasing physician awareness and education around the health harms of plastics and microplastics; conducting organizational audits to identify ways to reduce the use of unnecessary single-use plastics; physicians raising awareness about impacts of plastic-associated chemicals on human and environmental health with patients and the public; and increased research on the health harms of microplastics and nanoplastics.[15,69,70] This could include conducting longitudinal biomonitoring studies in human populations, including high-risk populations, to assess microplastics exposure, as well as longitudinal observational studies in human populations, including high-risk populations, to assess the impacts of microplastic exposure on human health.[4,11] Strategies for reducing waste within health care settings are described in further detail in the AMA Council on Science and Public Health report, *Promoting the Use of Multi-Use Devices and Sustainable Practices in the Operating Room*, adopted at the 2023 Interim Meeting of the AMA House of Delegates.[71]

U.S. POLICY AND REGULATORY LANDSCAPE

In the U.S., policies and regulations aimed at reducing single-use plastics, such as plastic bag bans or taxes, have been implemented, but these regulations or bans largely occur at the city or county level.[72] However, there are several jurisdictions with state-wide restrictions on plastic products (See Appendix C).[73] In general, most legislation around banning or restricting single use plastics is in the form of regulating plastic bags, though some states have begun regulating the use of other single-use plastic items, such as plastic bottles. This can range from an outright prohibition on plastic bags to allowing only plastic bags that meet certain requirements, to mandating a small charge per plastic bag a customer uses. Typically, there are also exceptions to these requirements that may include customers using SNAP benefits and/or some smaller retailers.[74,75] For places that implement a tax on single use plastic, such as a tax on plastic bags at grocery stores, they are generally used toward existing funds within the jurisdiction that pay for environmental clean-up or conservation efforts.[76] The effectiveness of single use plastic bans in the U.S. are, at this time, not well studied or documented. However, studies have indicated that plastic bag regulations lead to a 25 to 47 percent decrease in plastic bags at shoreline cleanups.[77,78] For a non-exhaustive, high-level summary of U.S. state and local regulations on single use plastics, which is intended to provide a snapshot of the range of current U.S. regulations, see Appendix C.

Some states have taken the opposite approach and enacted legislation that prohibits city and county governments from enacting restrictions on single-use plastics. These bans, sometimes referred to as "bans on bans," can be a total prohibition on any regulation or a prohibition on a total ban but may allow city and counties to impose a tax on single-use plastics.[79] Justification for these bans vary by state but some general reasons are plastic bags are largely reused, recycling is seen as a more effective solution, and plastic bags tend to carry less harmful bacteria than reusable bags.[79] Overall these justifications are not particularly compelling for several reasons. First, plastic recycling has proven to be an ineffective solution in reducing plastic waste in the U.S. Second, while reusable bags have been found to contain different types of bacteria, there have been very few known cases of reusable grocery bags being a source of infection and over 99 percent of bacteria can be removed through regular washing.[80,81] In fact, during the COVID-19 pandemic,

there were claims that reusable grocery bags could carry and transmit the virus, but those assertions were found to be false.[82]

In terms of regulating the chemicals within plastic, at the state level, in September 2024, California passed legislation that will end the use of intravenous medical supplies that contain Di(2-ethylhexyl) phthalate (DEHP), a plasticizer chemical commonly added to polyvinyl chloride that is suspected of being a human carcinogen. The law will go into effect in 2030 and is anticipated to affect the entire U.S. market with a few other states already proposing similar bills.[83] A similar ban on DEHP in IV bags has also been adopted in the European Union.[84]

At the federal level, the Microbead-Free Waters Act of 2015 prohibits the manufacture and sale of rinse-off cosmetic products containing plastic microbeads, such as exfoliants and toothpaste, across the U.S., requiring states with existing bans to align with this standard.[85] While the U.S. Environmental Protection Agency (EPA) has yet to enact direct bans on microplastics, as of 2024 it was funding research, developing analytical methods, and prepared a National Strategy to Prevent Plastic Pollution.[20,86] Additionally, the Agency for Toxic Substances and Disease Registry (ATSDR), in partnership with the Centers for Disease Control and Prevention (CDC), established a working group to investigate potential health impacts of microplastics, the current state of which is unknown due to recent federal funding cuts and agency reorganization.[87] Federal legislation such as the Save Our Seas Act and the Infrastructure Investment and Jobs Act provide funding support for microplastic monitoring, environmental cleanup efforts, and treatment technologies targeting emerging contaminants.[86] These federal initiatives complement state-level plastic regulations by addressing the growing concerns around microplastic pollution and its broader environmental and public health effects.

Additionally, S.3127, the "Break Free from Plastic Pollution Act," proposed in 2023 but not passed, was comprehensive federal legislation aimed at significantly reducing plastic pollution nationwide.[88] It proposed a national ban on certain single-use plastic products, including single-use plastic bags, straws, utensils, and foodware, while promoting producer responsibility and funding for waste management improvements. The bill proposed to require manufacturers to reduce plastic production and implement reuse and recycling programs.[88]

There have also been recommendations to improve the Toxic Substances Control Act (TSCA) to address the lack of safety information on chemical additives in plastic. TSCA is a federal law passed in in 1976 which provides the U.S. EPA with the authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures.[89] As opposed to a "precautionary principle" approach, TSCA's framework assumes that a chemical is considered safe until proven unsafe and the onus of proving harm is on the U.S. EPA, as opposed to the chemical manufacturer. This approach is different from the European Union's chemical regulation approach, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Within the EU REACH program, the responsibility of data generation, risk assessment, and risk management is the responsibility of industry, and they are more proactive in restricting the use of chemicals that are suspected to be unsafe.[90]

The TSCA inventory includes 83,000 chemicals and is continually updated as new chemicals are commercially manufactured or imported. Out of these 80,000+ chemicals, the EPA has only banned nine chemicals in the past four decades, and only about 200 have been tested for safety.[91–93] Reform of TSCA was signed into law in 2016 by President Obama, which amended TSCA to require EPA to conduct risk evaluations of chemicals on a specified schedule starting with those likely to pose health risks (there was no requirement prior), to consider risks to "potentially exposed or susceptible subpopulations," and determine if a chemical poses an "unreasonable risk" without consideration of cost.[94] The 2016 legislation also required EPA to regulate any existing chemical determined to pose an unreasonable risk "to the extent necessary so that the chemical substance or mixture no longer presents such risk" and empowered the EPA to require manufacturers to perform additional safety testing if more data is needed.[91,94] Despite these amendments to TSCA, there is still concern that the legislation does not go far enough to proactively addressing health safety and concerns of chemicals in the U.S.[90,91]

Recommendations on how TSCA can further be improved to protect health and safety include: (1) considering all conditions of use and exposure pathways for chemicals, in other words, consider cumulative impacts of chemicals; (2) quantifying exposures across pathways and populations; (3) better identifying and protecting potentially exposed or susceptible subpopulations; (4) gathering health and toxicity data to fill data gaps; and (5) using validated systematic review methodology in chemical assessments.[91]

CURRENT AMA POLICY

AMA has existing policy supporting sustainability efforts in health care, which includes policy promoting multiple-use equipment versus single-use equipment, as well as policy calling for a ban on plastic microbeads. AMA has several policies on chemical additives common in plastics, including PFAS, BPA, and phthalates that call for continued research, robust evidence-based regulatory frameworks. In the case of Policy H-135.945, "Encouraging Alternatives to PVC/Phthalate Products in Health," the AMA calls for a phasing out of polyvinyl chloride products with Di(2-ethylhexyl) phthalates in health care settings.

Existing AMA Policy D-135.976, "Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976" calls on the AMA to advocate for modernizing the TSCA to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Furthermore, resolution 429-A-25, "Addressing the Health Consequences of Microplastics in Humans," was adopted by the House of Delegates.[1] This new policy recognizes the potential health risk of microplastics, encouraged increased research on the topic, called on AMA to support respective medical specialties and other relevant organizations to develop evidence-based guidelines for monitoring and mitigating microplastic exposure in water, food, air, and other consumer products, and for AMA to collaborate with relevant parties to promote public education on microplastics.

CONCLUSION

Plastic poses serious environmental and human health concerns across its lifespan because it is primarily derived from fossil fuels, contains thousands of chemicals added during its production, is not easily recycled, and very slowly degrades in the environment. Plastic production, and consequently the volume of plastic waste, has grown exponentially over the last fifty years, threatening ecosystems and public health across the globe. There are several policy levers that can be employed across all levels of government and within institutions to reduce the burden of plastic pollution, the most impactful being to limit the amount of plastic being produced and used in the first place. Other strategies include improved waste management and recycling systems as well as the use of bioplastics as an alternative to synthetic plastics. Additionally, more research is needed to better understand the effectiveness of policies that limit the use of single-use plastic products as well as the health impacts of microplastics and the chemicals found in plastics.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That Policy H-135.901, "Addressing the Health Consequences of Microplastics in Humans" be amended by addition and deletion to read as follows:

ADDRESSING THE HEALTH CONSEQUENCES OF <u>PLASTICS AND</u> MICROPLASTICS IN HUMANS

1. Our American Medical Association recognize the potential health risks associated with <u>plastics and</u> microplastics ~~exposure~~ and encourage increased research to better understand the human health effects <u>and environmental impacts</u> of <u>plastics across their lifespan</u> ~~microplastics~~<u>,</u> <u>including the chemicals used in plastic production</u>.
2. Our AMA supports the <u>development of</u> ~~respective specialty medical societies with subject matter expertise and federal and state public health agencies, including the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA), to develop~~ evidence-based

guidelines for monitoring and mitigating microplastic exposure in water, food, air, and other consumer products.
3. Our AMA will collaborate with relevant stakeholders to promote public education about microplastics, their sources, potential health risks, and possible strategies for reducing exposure.
~~4. Our AMA will study and report back with policy recommendations on ways to reduce plastic pollution and its impact on climate change and health, including but not limited to federal, state, and local taxes and limitations on the use of single-use plastic consumer products and other types of plastic, interventions to reduce microplastics, and alternatives to plastic.~~
4. Our AMA supports policies to reduce plastic pollution, such as limits on single-use plastics (for example plastic bags), incentivizing non-plastic alternatives such as reusable bags, food containers, and packaging, incentivizing alternative reformulations of synthetic plastics (such as bioplastics), and improving recycling infrastructure and systems to better manage plastic waste.

3. That Policy D-135.976, "Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976" be amended by addition and deletion to read as follows:

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; (3) advocate for the U.S. Environmental Protection Agency to consider the cumulative impacts of chemicals within their risk assessment process and quantify exposures across pathways and populations; ~~and~~ (~~3~~4) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), and (5) support the proactive restriction or phasing-out of chemicals suspected of posing significant health risks.

Fiscal Note: Minimal – less than $1,000.

APPENDIX A - GLOSSARY

Bisphenols	Bisphenols represent a group of industrial chemicals used in plastic production to make hard, clear plastic (such as water bottles or baby bottles). They are also used as protective coatings on the inside of food and beverage cans.
Brominated chemicals	Compounds that contain bromine (a naturally occurring element), which helps reduce product flammability.
Cracking	A petrochemical process in which saturated hydrocarbons are broken down into smaller, often unsaturated, hydrocarbons known as olefins, that are then made into plastic resins.[51]
Ethane	A colorless, odorless, and flammable hydrocarbon gas, that is a key component of natural gas.
Ethylene	A colorless, flammable hydrocarbon gas that serves as a key industrial chemical in making plastics and industrial chemicals.
Fracking	Otherwise known as hydraulic fracking, this is a method of extracting natural gas and oil from deep shale rock formations using forced water, sand, and a mix of chemicals into horizontally drilled wells.
Hydrocarbons	Organic compounds composed entirely of carbon and hydrogen atoms; the primary components of fossil fuels.
Microplastics	Pieces of plastic that range in size but are less than 5 millimeters which are produced in two ways: (1) through the breakdown or degradation of larger plastic materials, or (2) intentionally manufactured at that size for use in consumer products.
Monomer	An individual network of atoms or molecules that are chemically united together to form a polymer.
Nanoplastic	Pieces of plastics smaller than 1 micrometer

Perfluoroalkyl and polyfluoroalkyl chemicals	Also known as PFAS chemicals, represent a large group of synthetic chemicals that are broadly defined by their chain of linked carbon and fluorine atoms. The strength of the carbon and fluorine chemical bond makes PFAS chemicals persistent with our environment and they do not break down easily, hence why they are known as "forever chemicals." PFAS chemicals are a common component in many plastic consumer products, such as food packaging, clothing, and cosmetics, as they help create grease and water-resistant surfaces
Phthalates	A class of synthetic chemicals that are widely used in consumer products; are added to plastics to increase their flexibility, transparency, durability, and longevity.
Polymer	A large molecule that is made up of many repeating, smaller units (or monomers), and creates a network-like chemical structure.
Polypropylene	A versatile and widely used plastic found in many products, including food storage containers. Polyethylene is the most widely used plastic in the world found in many everyday products, such as plastic bags, plastic containers, and medical tubing.
Propylene	A colorless, flammable gas used as a chemical intermediate in the production of various substances, including polypropylene plastic applications.
Vinyl Chloride	A colorless, flammable gas that is primarily used to make hard plastic resin commonly found in plastic pipes and packaging materials

APPENDIX B - FIGURES

Figure 1. Historical Global Plastic Production[95]

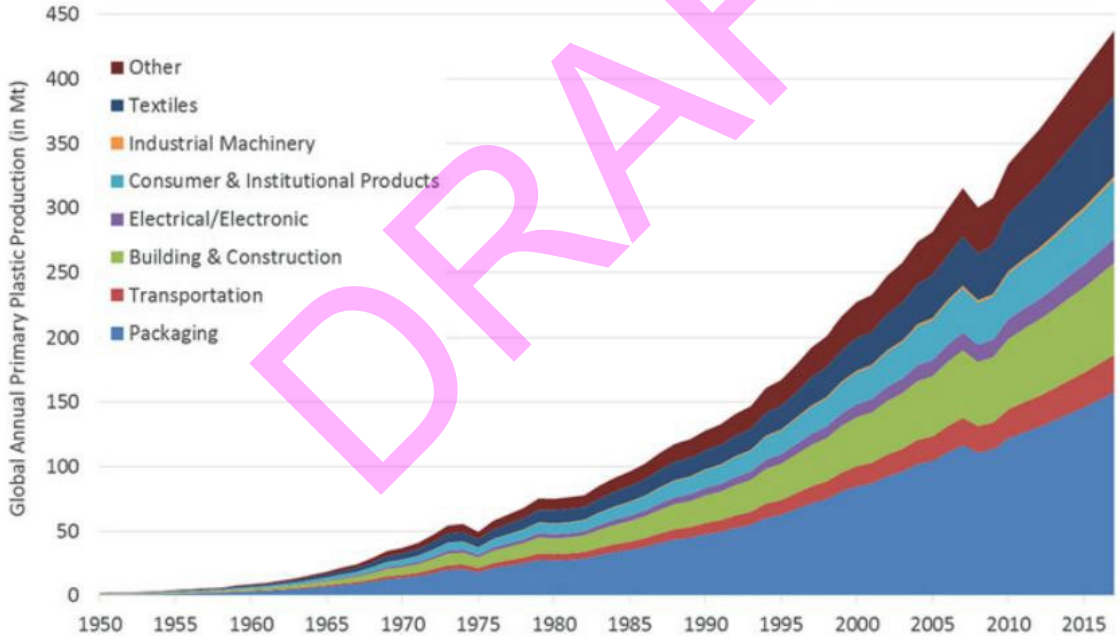


Figure 2. Health Impacts of Plastic Across its Life Cycle[4]

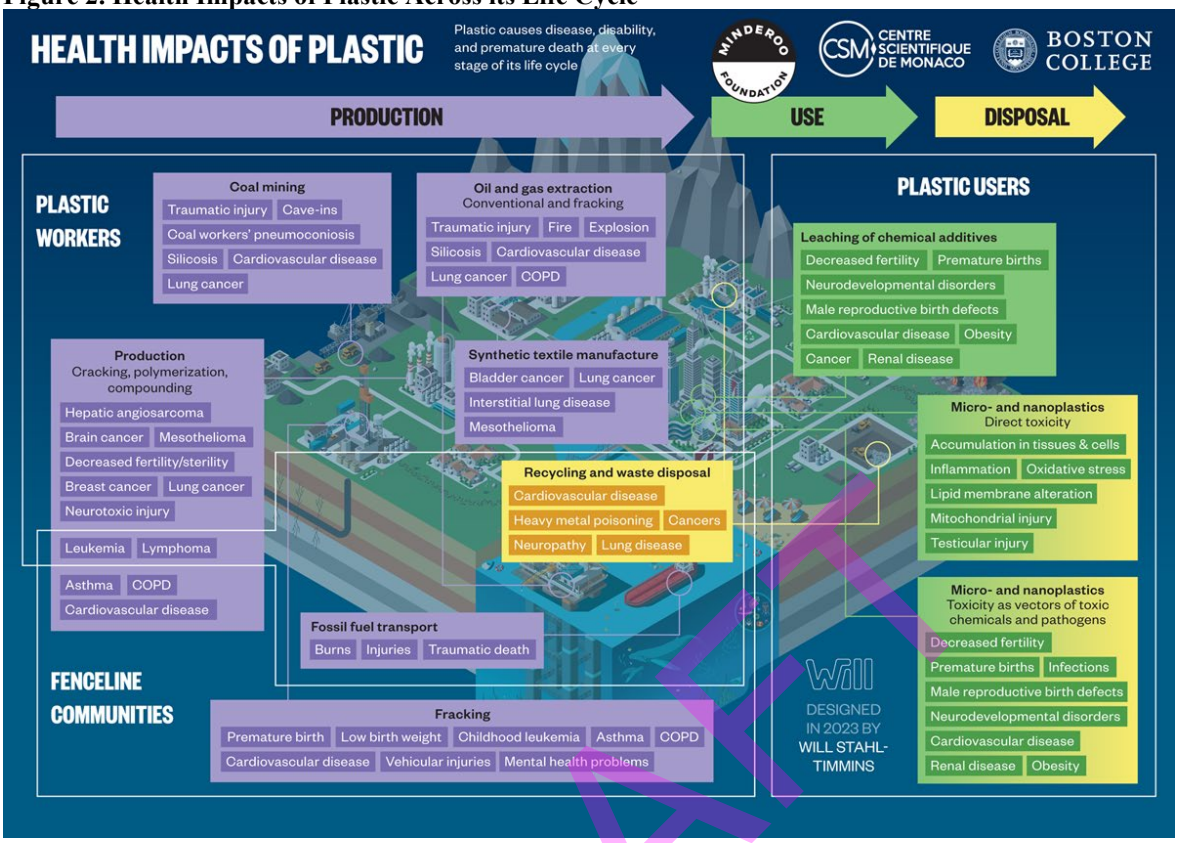
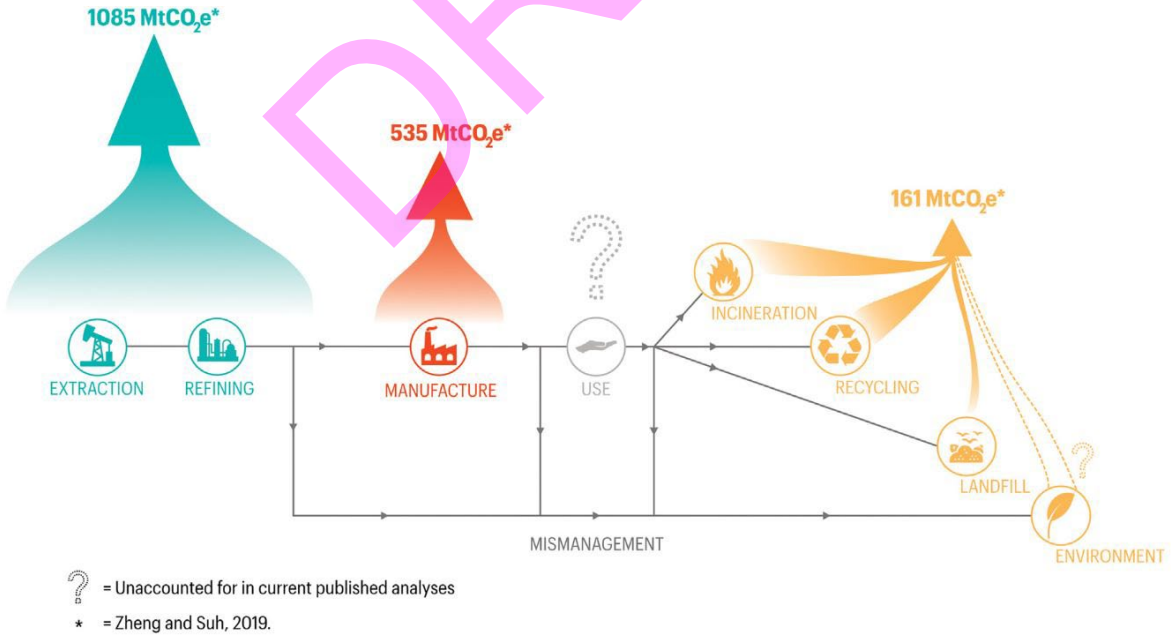


Figure 3. Visualization of the estimated amounts of greenhouse gases released at each stage of the plastic life cycle.[51]



APPENDIX C – ADOPTED U.S. STATE AND LOCAL LEGISLATION ON PLASTIC PRODUCTS AS OF JUNE 2025

State	Summary of Legislation on plastics
Alaska	A majority of Alaskan communities, including Anchorage with code 15.95.020, have banned plastic bags unless they meet a certain requirement, such as being a certain thickness.[96]
Arizona	State law, SB 1241, bans any county, city, or town from "impos(ing) a tax, fee, assessment, charge" on "auxiliary containers" which includes bags, bottles, cups, and other containers made out of plastic.[97]
Arkansas	State law prohibits a municipality or county to "restrict, tax, prohibit, or otherwise regulate the use, disposition, or sale" of containers that are made out of plastic (Act 751 of the 93rd General Assembly).[98]
California	In August 2014, California became the first state to enact legislation imposing a statewide ban on single-use plastic bags at large retail stores. Additionally, by 2032, there must be a 25 percent decrease in single-use plastic packaging and food ware in the state, all single-use packaging and plastic ware must be recyclable or compostable and must recycle 65 percent of single-use plastic packaging and food ware.[99]
Colorado	With only a few exceptions, as of January 1, 2024, no store or retail food establishment can provide single-use plastic carryout bags to customers. There is also now a minimum of a 10-cent fee for recycled paper carryout bags.[100]
Connecticut	As of July 1, 2021, the state adopted a ban on stores providing or selling single-use checkout bags to customers (CT Gen Stat. Section 22a-246a).[101]
Delaware	As of Jan 1, 2021 store that has a single location of at least 7,000 square feet or has 3 or more locations each having at least 3,000 square feet of retail space cannot provide any single-use plastic carryout bags (Section 6099A). Additionally, other stores shall "adopt practices to eliminate the need for plastic carry out bags" and plastic bag manufacturers shall provide stores with recycling opportunities and educational programs for plastic bag and film recycling (7 DE Admin. Code 1301).[102,103]
Florida	State law prohibits local governments from regulating, taxing, or banning auxiliary containers, disposable plastic bags, or wrappings. However, Miami-Dade County circumvented this preemption by passing legislation that only applies to public places and eliminated single-use plastics and Styrofoam at Miami-Dade County facilities, including Miami International Airport.[104,105]
Georgia	Atlanta bans "non-compostable single-use serviceware" which includes plastic bags and plastic straws and South Fulton city bans single-use plastic bags in retail establishments.[106,107]
Hawaii	A few islands like Oahu have banned plastic bags and charge a minimum of 15 cents for recyclable or reusable bags.[108]
Idaho	State law prohibits any "regulation regarding the use, disposition or sale or any imposition of any prohibition, restriction, fee imposition or taxation" of containers that are designed for one-time use made out of plastic that is not made by the state legislature (Statute 67-2340).[109]
Illinois	Effective July 1, 2025, state legislation bans a hotel with 50 or more rooms to provide small, single-use plastic bottles with personal care products. Many cities have enacted their own legislation to either ban plastic single-use bags (see Evanston) or charge a small fee per single-use plastic bag (see, for example, Chicago).[75,110,111]
Indiana	State law, passed in 2016, bans local governments from taxing or restricting the use of disposable plastic bags by retailers.[112,113]
Iowa	State law prohibits counties to "adopt an ordinance, motion, resolution, or amendment that sets standards or requirements regarding the sale or marketing" of merchandise, including containers made out of plastic that are "used for consuming, carrying, or transporting" (HF 295).[114]
Kansas	Lawrence is the only city in Kansas with single-use plastic legislation. The city bans single-use disposable plastic bags with Ordinance No. 9996.[115]
Maine	With some limited exceptions, Maine bans retail establishments from providing single-use carry-out bags to customers (see 39 Maine Rev. Stat. Section 1611).[116]

Maryland	As of May 13, 2025, state law requires certain producers, including plastic producers, to increase recycling rates and develop more sustainable packaging designs (MD SB 901). Additionally, many counties and cities have banned retail establishments from providing single-use plastic carry-out bags.[117]
Massachusetts	As of June 2025, Massachusetts has pending legislation (Bill S2541) that would ban single-use plastic carry-out bags statewide and require a minimum 10-cent fee on paper or reusable bags, with half of the fee directed to environmental protection efforts. The bill also proposes limiting plastic use by requiring straws and plasticware only upon request, banning the sale of small plastic water bottles (1 liter or less) and 100ml plastic alcohol containers (with exceptions for health, safety, and emergencies), and prohibiting state agencies from purchasing single-use plastic bottles. Additional provisions include a statewide recycling program for large plastic items like car seats, mandatory "Do Not Flush" labels on non-flushable wipes, development of a public composting plan, creation of an Environmental Protection Trust Fund, and a Producer Responsibility Commission to recommend extended packaging waste reduction strategies.[118]
Michigan	State law bans municipalities from "regulating, prohibiting or adding fees to the use or sale" of single-use plastic products.[112]
Minnesota	State law prohibits any counties and cities from imposing any ban "upon the use of paper, plastic, or reusable bags for packaging of any item or good purchased from a merchant, itinerant vendor, or peddler" (section 471.9998). Alternatively, some cities have adopted a five-cent tax on single-use plastic bags (see, for example, Minneapolis, Duluth, and Edina).[119–121]
Mississippi	State law bans a county or municipality from regulating the use, disposition or sale or imposing a fee on packaging made out of plastic, regardless of if it's single-use or reusable (SB 2570).[112]
Missouri	State law prohibits any county, city, town or village to "impose any ban, fee, or tax upon the use of either paper or plastic bags for packaging of any item or good purchased from a merchant, itinerant vendor, or peddler" (Section 260.283).[122]
Montana	State law bans any local unit of government from adopting any policies that would prohibit, restrict, or regulate (including imposing a fee) on plastic products (HB 407).[123]
Nevada	Nevada has no statewide ban on single-use plastics, but several local jurisdictions have enacted restrictions, including a retailer plastic bag distribution ban effective January 1, 2022. Senate Bill 324 bans the sale of water in disposable plastic bottles (4 liters or less) in communities near Lake Tahoe.[124]
New Jersey	New Jersey currently enforces one of the most comprehensive statewide bans on single-use plastics through P.L. 2020, c.117, which became fully effective on May 4, 2022. The law prohibits single-use plastic carryout bags at all retail and food service establishments and bans paper bags in grocery stores over 2,500 square feet. Polystyrene foam food containers are also banned, with all exemptions having expired by May 2024. Plastic straws are allowed only upon customer request, per provisions in effect since November 4, 2021. The law is enforced through progressive penalties, ranging from warnings to fines of up to $5,000 per day. By 2023, it had already led to the elimination of 5.5 billion plastic bags and 110 million paper bags, while contributing to a 37% reduction in shoreline plastic litter and an 88% decrease in plastic straw distribution.[125]
New York	New York currently enforces a statewide ban on single-use plastic bags through the Bag Waste Reduction Act, effective since March 1, 2020. It prohibits retail and food service businesses from distributing plastic carryout bags and requires a minimum 5-cent charge for paper bags.[126]
North Carolina	State preemption law prohibits local governments from enacting their own plastic bag restrictions.[127]
Oregon	Oregon enforces a statewide ban on single-use plastic bags under House Bill 2509, effective January 1, 2023. The law prohibits most retailers, including grocery stores, restaurants, and other retail locations, from providing single-use plastic checkout bags and requires a minimum fee for paper alternatives. Senate Bill 543 expands Oregon's plastic reduction efforts by phasing out polystyrene foam food ware, packing peanuts, and coolers, and banning PFAS in

	food packaging starting January 1, 2025. By 2027, single-use plastic bags will be fully phased out at all checkout lanes statewide.[128]
Rhode Island	Rhode Island enforces a statewide ban on single-use plastic bags at retail establishments under the Plastic Waste Reduction Act, which took effect on January 1, 2024. The law establishes a uniform statewide standard and encourages consumers to use reusable bags. Paper bags may still be offered at some stores, but plastic checkout bags are not allowed.[129]
South Carolina	North Myrtle Beach became the 15th municipality to adopt a plastic bag ban, effective October 1, 2022. Charleston and at least 10 other coastal communities have banned plastic bags, straws, and foam containers.[130]
South Dakota	South Dakota prohibits local governments from regulating or banning single-use packaging under Codified Law 34A-6-92. This statute preempts municipal action on plastic bags, straws, beverage containers, and other packaging materials, aiming to maintain regulatory consistency statewide.[131]
Texas	Although some cities previously enacted local bans, a 2018 Texas Supreme Court ruling invalidated these ordinances, citing conflict with the state's Solid Waste Disposal Act. As a result, municipalities are prohibited from regulating the sale or use of containers, including plastic bags.[112]
Utah	Several municipalities such as Park City and Moab have implemented local restrictions on plastic bags and polystyrene containers. A 2023 update to Utah's bottle bill allows redemption center workers to sort containers by material type starting in 2025, supporting broader recycling efforts.[132]
Vermont	Vermont does not ban plastic bags outright but has passed legislation requiring retailers to charge a five-cent fee on both plastic and paper bags beginning July 1, 2024. The state has enacted laws and regulations to address single-use plastic bag usage, including a ban on plastic carry-out bags, the implementation of the five-cent fee on paper bags, and supporting public education initiatives to promote the use of reusable alternatives.[133,134]
Virginia	Virginia issued Executive Order 77, which mandates that all state agencies eliminate the use of disposable plastic bags and single-use foodware within 120 days of implementation. This executive order also required a full phase-out of other single-use plastics in state agencies and public universities by the year 2025. To note, this executive order was later repealed by a subsequent governor. Additionally, Virginia enacted legislation that bans single-use polystyrene foam containers statewide beginning July 1, 2025. Although the state does not currently have a plastic bag ban that applies broadly to retail businesses, House Bill 1757, passed in 2020, grants local governments the authority to enact their own fees or bans on plastic bags. Several municipalities in Virginia have already passed ordinances utilizing this authority, and enforcement is managed by the Virginia Department of Environmental Quality.[135]
Washington	Washington has enacted a statewide ban on single-use plastic bags that took effect on October 1, 2021, under Senate Bill 5323 passed in 2020. Retailers are prohibited from providing single-use plastic bags to customers and must charge an eight-cent fee for paper or reusable bag alternatives. A newer law signed in 2025 increases penalties related to plastic waste and permits retailers to offer thicker bags for sale beginning January 1, 2026, through the year 2028. Enforcement of these regulations is carried out by the Washington State Department of Ecology, and the law is recognized as one of the most comprehensive bans in the United States.[136]
Wisconsin	While municipalities previously had authority to regulate single use plastics, the 2015 Wisconsin Act 302 now prohibits local governments from enacting bans or fees.[137]
Wyoming	Local governments such as the Town of Jackson and Teton County have implemented ordinances banning single-use plastic bags and requiring a twenty-cent fee for paper or reusable alternatives. These fees support local waste reduction programs.[138]

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