CANCER PEDIA

POLICY AND REGULATION

LICENSING, REGULATION AND ACCREDITATION

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CHAPTER
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LICENSING, REGULATION AND ACCREDITATION

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A. INTRODUCTION

Governments, associations, professional organizations, networks and other groups set licensing requirements, regulations and accreditation standards to govern cancer control activities and the safe delivery of cancer care services. These may be developed at the international, national or subnational (regional/state/provincial) levels, and influence the development of policies, standards and best practices.

This chapter presents an overview of licensing, regulation and accreditation bodies in four key areas related to cancer control and cancer care services: carcinogens and carcinogenic exposure; health and technical professionals; health service organizations; and the development of licensing, regulatory and accreditation requirements.

B. CARCINOGENS AND CARCINOGENIC EXPOSURE

1. CLASSIFICATION OF CARCINOGENS

Carcinogens are substances and exposures that can induce the formation of cancer. Carcinogens can be physical (e.g., ultraviolet and ionizing radiation), chemical (e.g., asbestos, aflatoxin, arsenic) and biological (e.g., infections from viruses, bacteria and parasites).[1] The way in which carcinogens contribute to the formation and development of cancer varies. Some carcinogens directly affect a person's DNA, while others cause cells to divide more rapidly than normal.[2] Carcinogens also have different levels of cancer-inducing potential; the risk of forming cancer is influenced by many factors, including the duration and intensity of the exposure.

Several international and national organizations conduct research on substances, agents, mixtures and exposures to determine their cancer-inducing potential. These agencies also determine how carcinogens are classified.

As an integral part of the World Health Organization, the International Agency for Research on Cancer (IARC) plays a major role promoting international collaboration in cancer research. IARC provides the most commonly used system for carcinogen classification and serves as a global reference for cancer information.[2,3]

Based on rigorous scientific reviews and evaluations, IARC categorizes agents into one of five categories based on exposure data, human cancer studies, experimental animal cancer studies, and mechanistic and other relevant data.[4]

Group 1: Carcinogenic to Humans

Substances in Group 1 show sufficient evidence of carcinogenicity in human studies. Other substances may be included in Group 1 if there is less than sufficient evidence of carcinogenicity in human studies, but sufficient evidence of carcinogenicity in experimental animals and strong evidence of relevant mechanisms in cancer formation and development in human studies.

Group 2A: Probably Carcinogenic to Humans

Generally, Group 2A substances show limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. This group may also include substances that show inadequate evidence of carcinogenicity in clinical studies, but sufficient evidence of carcinogenicity in animal studies and strong evidence of carcinogenesis mechanisms in exposed humans. In rare cases, substances may be classified as 2A based exclusively on limited evidence of carcinogenicity in human studies.

Group 2B: Possibly Carcinogenic to Humans

Substances in Group 2B demonstrate limited evidence of carcinogenicity in human studies and less than sufficient evidence of carcinogenicity in animal studies. This group also includes substances with inadequate evidence of carcinogenicity in clinical studies, but sufficient evidence of carcinogenicity in animal experiments, with supporting mechanistic and other relevant data. Substances may also be included in this category based on strong evidence of carcinogenicity from mechanistic and other relevant data.

Group 3: Unclassifiable as to Carcinogenicity in Humans

Substances with inadequate evidence of carcinogenicity in human studies and inadequate or limited evidence of carcinogenicity in animal studies are categorized as Group 3. Substances may also be included in this category when evidence of carcinogenicity is inadequate in clinical studies, but is sufficient in experimental animals and is supported by strong evidence that the mechanisms of carcinogenicity in experimental animals do not operate in humans. Group 3 substances often require more research to determine their carcinogenicity and overall safety upon exposure.

Group 4: Probably Not Carcinogenic to Humans

Group 4 substances show evidence suggesting a lack of carcinogenicity in human and animal studies. In some cases, substances may be included in this group if they show inadequate evidence of cancer development in humans and evidence of a lack of carcinogenicity in animal experiments, which are consistently and strongly supported by mechanistic and other relevant data.

As of January 2018, IARC had evaluated the cancer-inducing potential of 1003 agents and categorized them accordingly, as outlined in Table 1.[5]

Table 1: Agents in the IARC Classification System[5]

Categories	Descriptions	Number of Agents
Group 1	Carcinogenic to humans	120
Group 2A	Probably carcinogenic to humans	81
Group 2B	Possibly carcinogenic to humans	299
Group 3	Unclassifiable as to its carcinogenicity to humans	502
Group 4	Probably not carcinogenic to humans	1

Other examples of international and national systems used to identify and classify carcinogens are:

- The United Nations' Globally Harmonized System of Classification and Labelling of Chemicals, which aims to provide a standardized chemical hazard classification system for all countries.[6]
- The American Conference of Governmental Industrial Hygienists' Threshold Limit Values for occupational exposures, monographs on workplace chemical hazards and Biological Exposure Indices for chemical substances.[7]
- The United States' Department of Health & Human Services' National Toxicology Program, which evaluates agents of public health concern by developing and applying tools of modern toxicology and molecular biology.[8]
- The United States' Environmental Protection Agency (EPA) and its Integrated Risk Information System, which includes important information on human health effects from environmental exposure to certain substances.[9]
- Safe Work Australia's Approved Criteria for Classifying Hazardous Substances, which provides the mandatory criteria for determining whether a substance is hazardous based on its health effects.[10]

Since many of these agencies act independently, numerous known or suspected carcinogens have been examined using different classification systems. As a result, carcinogenic substances may appear in multiple classification systems. Similarly, some substances may only appear in one classification system. This does not suggest controversy or disagreement; rather, it may indicate that certain substances have yet to be full examined and evaluated.

Over the past five decades, science has moved towards a more continuous view of carcinogens, recognizing that not all carcinogens are harmful at very low exposures, whereas others are lethal at higher doses. More sophisticated views of carcinogenicity use a risk framework that considers dose, potency, exposure duration, and other factors. There is work in motion to build up a standardized and robust methodology for the assessment of carcinogenicity.[11]

2. GOVERNMENT REGULATION FOR EXPOSURES

Governments implement legislative and regulatory measures to limit environmental and occupational exposure to carcinogens. Governments also implement threshold limits and guidelines to reduce the harmful effects of radiation, and many have rigorous review processes to ensure the safety and effectiveness of cancer drugs. These areas are described briefly below, along with selected examples of governments that have implemented regulatory measures for each type of exposure.

Environmental Exposure to Carcinogens

Environmental carcinogens are physical, chemical and biological agents in the surroundings of individuals that induce the development of cancer. Many toxic pollutants in the air, soil, water and food are carcinogenic and mutagenic, meaning they can change genetic material.[12]

Governments can implement regulatory measures to minimize such exposure. For example, the United States' EPA develops standards and sets regulations for air pollutants, water pollutants and pesticides to improve air quality, protect waters and assure the safety of chemicals.[13] The EPA is also responsible for compliance and enforcement, and has various programs to assist, monitor and encourage industry and businesses to meet environmental laws, standards and regulations.[14]

Other examples of governments that have implemented regulatory measures to minimize exposure to environmental carcinogens include:

- Environment and Climate Change Canada, which provides leadership for clean growth and climate change, environmental monitoring, science-based research, policy and regulatory development and minimizing threats from pollution.[15]
- The European Chemicals Agency, which helps companies to comply with legislation, promotes the safe use and handling of chemicals, and provides information about chemicals and their concerns.[16]
- The European Commission's Directorate-General for Environment, which plays an important role in the policy area of the environment for the European Union and its member states.[17]
- The European Environment Agency, which provides independent information on the environment.[18]

Occupational Exposure to Carcinogens

Occupational carcinogens are substances or agents that increase the risk of cancer upon exposure in workplace environments. The impact of these carcinogens can be significant.

Governments create national regulatory bodies to manage workplace health, safety and welfare. These bodies require employers to meet standards to protect the well-being of their employees. Workplace regulations may address exposure to chemical agents and chemical safety, as well as exposure to physical and biological hazards. Regulatory bodies are also responsible for compliance and enforcement, which may range from training and education to investigating violations or filed complaints, issuing penalties and prosecution.

Some examples of governments that have implemented regulatory measures to minimize exposure to occupational carcinogens include:

- The United States' Occupational Safety and Health Administration, which is responsible for workplace health and safety regulations.[19]
- The United States Department of Labor's Mine Safety and Health Administration, which aims to prevent death, disease and injury from mining, and to promote safe and healthful workplaces for miners.[20]

- Health Canada, which sets national occupational health and safety legislation.[21]
- The European Agency for Safety and Health at Work, which produces directives that outline minimum requirements and fundamental principles for safety and health at work.[22]
- The United Kingdom's Health and Safety Executive, a non-departmental public body that is responsible for regulating workplace health and safety.[23]
- The Health and Safety Authority in Ireland, a national regulatory body for workplace safety, health and welfare.[24]

Radiation

Radiation is the emission of energy from any source. With sufficient energy, radiation can damage the DNA of cells, which may lead to cancer.

Radiation protection legislation and regulations address different sources of radiation by setting standards on exposure, emissions, management and disposal.[25] A number of government agencies regulate the use of nuclear energy and materials, and the management of radioactive waste, to protect public health and the environment. For example, Health Canada develops regulations, guidelines, standards and safety codes for radiation-emitting devices and inspects their safety in federally-regulated facilities. The United States' Food and Drug Administration also conducts inspections, criminal investigations, and other compliance and enforcement activities to ensure that its radiation regulations and standards are followed.[26]

Selected examples of governments that have implemented regulatory measures to minimize exposure to harmful levels of radiation include:

- The United States' EPA, which sets radiation protection laws and standards, and issues guidance.[27]
- The United States' Nuclear Regulatory Commission, which is primarily responsible for setting regulations, licensing, inspecting and enforcing compliance in relation to reactors, the use of nuclear materials and waste management.[28]
- The United States' Food and Drug Administration, which sets regulations for radiation-emitting products such as X-rays, mammograms, microwave ovens and cell phones.[29]
- The United States' Department of Energy, which addresses energy, environmental and nuclear challenges through transformative science and technology solutions.[30]
- Health Canada, which conducts research on the health effects of environmental and occupational radiation, and offers advice on radiation to agencies, industry and the general public.[31]
- The Canadian Nuclear Safety Commission, which regulates licensees, organizations, facilities and the activities operating inside nuclear energy facilities in Canada.[32]
- The European Commission on Radiation Protection, which has developed and implemented directives to protect human health against the dangers arising from ionizing radiation.[27]
- The International Commission on Radiological Protection, an independent, international organization with leading scientists and policy-makers in radiological protection, whose International System of Radiological Protection is used globally as the foundation for radiological protection standards, legislation, guidelines, programs and practices.[33]

Cancer Drugs

Drugs that can destroy cancer cells are used in chemotherapy, hormone therapy and other biological therapies. All cancer drugs have the potential to harm healthy cells in addition to cancer cells.

Governments are obligated to ensure the safety, quality and efficacy of cancer drugs to protect the health of their citizens. Requirements for scientific evidence in pre-clinical studies and human clinical trials, as well as post-market surveillance and inspection, can help to prevent undue harm and identify adverse reactions and unsuspected health risks. Drugs deemed unsafe or harmful should have had their clinical indications changed or be removed from the market.

Examples of agencies that have implemented regulatory measures in relation to cancer drugs include:

- The United States Food and Drug Administration's Center for Drug Evaluation and Research, which manages the nation's development and approval process for drugs.[34,35]
- Health Canada's Health Products and Food Branch, which is responsible for reviewing new therapeutic products in Canada and evaluating their safety, efficacy and quality.[36]

- Canada's Patented Medicine Prices Review Board, which ensure that manufacturers' prices of patented medicines sold in Canada are not excessive and reports to the Parliament of Canada on the price trends of all medicines.[37]
- The Canadian Agency for Drugs and Technology in Health, which provides information to decision-makers on the clinical effectiveness and cost-effectiveness of health technologies.[38]
- The European Medicines Agency, which protects and promotes public and animal health by evaluating and supervising medicines for human and veterinary use.[22]
- The United Kingdom's Medicines and Healthcare Products Regulatory Agency, which is responsible for drug licensing.[39]
- The Italian Medicines Agency, which acts as the national authority for drug regulation.[40]
- Sweden's Medical Products Agency, which acts as the national authority for the regulation and surveillance of drugs and other medicinal products development, manufacturing and marketing.[41]

C. HEALTH AND TECHNICAL PROFESSIONALS

A wide array of medical and health professionals provide cancer care services. These professionals require specialized training to be licensed to practice, and may require additional skills and expertise related to cancer care. Professional licensing ensures that individuals have the appropriate knowledge and skills to fulfil their responsibilities safely.

Governments oversee the licensing of health professionals may do so through national or subnational bodies or regulations. Examples include:

- The Royal College of Physicians and Surgeons of Canada, which sets the standards for specialty medical education in Canada, supports continuous learning for specialist physicians, and promotes health policy.[42]
- American College of Surgeons, which strives to improve the care of the surgical patient and safeguard standards of care in an optimal and ethical practice environment.[43]
- The General Medical Council in the United Kingdom, which is responsible for registering and licensing medical doctors to practice medicine.[44]
- The Canadian Association of Medical Radiation Technologists, which is a national professional association and certifying body for medical radiation technologists and therapists.[45]
- The Royal College of Radiologists, which works to improve the standard of practice in radiology and oncology in the United Kingdom.[42]
- The *Ontario Regulated Health Professions Act* in Canada, which governs all health professionals in the province through profession-specific legislation.[46]

These bodies may also be responsible for continuing medical education programs, as well as monitoring and maintaining standards of practice through peer assessment and remediation.

For additional information on the licensing and education of professionals who provide specific clinical cancer services, please refer to other *Cancerpedia: Clinical Services* and *Core Services/Infrastructure* chapters.

D. HEALTH SERVICE ORGANIZATIONS

Governments and other organizations regulate the quality of academic cancer hospitals, community hospitals and specialized centres through accreditation. Accreditation aims to ensure that facilities are operating in the best interests of the public and includes: evaluating and improving healthcare services in relation to standards of excellence; setting standards and promoting activities related to cancer prevention, research, education and quality of care; and developing information and guidelines on cancer, cancer care and treatments relating to cancer detection, prevention and risk reduction, supportive care and other areas.

Examples of agencies that accredit healthcare organizations include:

- The American College of Surgeons' Commission on Cancer, which accredits cancer programs, sets standards and promotes activities related to cancer prevention, research, education and quality of care.[47]
- The United States Joint Commission, an independent, non-profit organization that has accredited and certified nearly 21,000 healthcare organizations and programs in the country.[48]

- The National Comprehensive Cancer Network in the United States, a non-profit alliance of leading cancer centres, with a goal to improve the quality and effectiveness of care for cancer patients.[49]
- Accreditation Canada, a non-profit, independent organization that uses an external peer review process to evaluate and improve the services of healthcare organizations in relation to standards of excellence.[3]
- Quality Health Advice Trent Accreditation, a private British healthcare company that is focused on improving quality, reducing risk and making services available at a reasonable price.[50]
- The Australian Council on Healthcare Standards, an independent, non-profit organization that leads healthcare assessment and accreditation nationally.[51]
- The International Society for Quality in Health Care, which support continuous improvement in the safety and quality of healthcare worldwide.[52]

For additional information on accreditation requirements of specific clinical cancer services, please refer to other *Cancerpedia: Clinical Services* and *Core Services/Infrastructure* chapters.

E. DEVELOPING LICENSING, REGULATION AND ACCREDITATION REQUIREMENTS

There are organizations whose work plays a key role informing the development of policies and standards for licensing, regulation and accreditation. These organizations may fund or conduct research, facilitate forums, host expert panels or support other activities.

Examples of organizations that play this important role include:

- The Federation of Medical Regulatory Authorities of Canada, a national organization of provincial and territorial medical regulatory authorities with a mission to advance medical regulation on behalf of the public.[53]
- The National Cancer Institute, the principal agency for cancer research and training in the United States.[54]
- The United States' National Institute of Environmental Health Sciences, a research institute that engages in, funds and facilitates fundamental research, exposure research, translational science, and research on health disparities and global environmental health.[55]
- The National Institute for Occupational Safety and Health of the United States Centers for Disease Control and Prevention, a federal agency that conducts research on, and makes recommendations for, the prevention of work-related injury and illness.[56]
- Canada's Safe Environments Directorate, which identifies and assesses the health risks posed by environmental factors.[57]
- The United Kingdom's National Cancer Research Institute, a partnership of major cancer research funders that promotes collaborative cancer research.[58]

For additional information on accreditation requirements of specific clinical cancer services, please refer to other *Cancerpedia: Clinical Services* and *Core Services/Infrastructure* chapters.

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