

## LIFE SCIENCES LIABILITY POLICY GLOSSARY OF DEFINED TERMS

The following defined words shall have the same meaning throughout this policy, whether expressed in the singular or the plural. Wherever appearing in bold print in this policy:

**ADVERTISEMENT**

**Advertisement** means a notice that is broadcast or published to the general public or specific market segments about the **Insured Entity's** goods, products or services for the purpose of attracting customers or supporters. For the purposes of this definition:

- A. notices that are published include material placed on the Internet or on similar electronic means of communication; and
- B. regarding web-sites, only that part of a web-site that is about the **Insured Entity's** goods, products or services for the purposes of attracting customers or supporters is considered an **advertisement**.

**ADVISORY MEMORANDUM**

**Advisory memorandum** means a written communication issued by the **Insured Entity** or on its behalf to healthcare professionals, customers, product users, suppliers, vendors or the public at large informing them of an actual or alleged defect or deficiency in an **insured product** or in its labeling. An **advisory memorandum** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

**APPLICATION**

**Application** means all signed applications for this policy and for any policy in an uninterrupted series of policies issued by the Insurer or any affiliate of the Insurer of which this policy is a renewal or replacement. **Application** includes any materials submitted or required to be submitted therewith. An "affiliate of the Insurer" means an insurer controlling, controlled by or under common control with the Insurer.

**ASBESTOS**

**Asbestos** means the mineral in any form whether or not the **asbestos** was at any time airborne as a fiber, particle or dust, contained in or formed a part of a product, structure or other real or personal property, carried on clothing, inhaled or ingested, or transmitted by any other means.

**AUTOMOBILE**

**Automobile** means a land motor vehicle, trailer or semi-trailer designed for travel on public roads, including any attached machinery or equipment. But **automobile** does not include **mobile equipment**.

**BIOLOGICAL PRODUCTS**

**Biological products** mean any virus, therapeutic serum, toxin, antitoxin, or analogous product that is:

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary, and any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or any function of the human body; or
- C. is a component of any product described in paragraph A. or B. above.

However, **biological product** does not include any **pharmaceutical drug**, **medical device**, **nutraceutical** or food.

**BODILY INJURY**

**Bodily injury** means bodily injury, sickness or disease sustained by a person, including death resulting from such injuries. **Bodily injury** also means mental injury, mental anguish or shock sustained by that person as a result of such bodily injury, sickness or disease. **Bodily injury** also means bodily injury, sickness, disease, mental injury, mental anguish or shock sustained by any relative of that person as result of such **bodily injury**.

**BOXED WARNING**

**Boxed warning** means any notice required by the Food and Drug Administration pursuant to 21 CFR 201. 57(a) (4) and (c) (1) or by any foreign equivalent of such. A **boxed warning** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

**CIRCUMSTANCE**

**Circumstance** means an **incident** reported during the **policy period** from which an **executive officer** reasonably expects that a **claim** could be made.

**CLAIM**

**Claim** means:

- A. a demand for money or services; or
  - B. a civil proceeding or an arbitration proceeding or any appeal therefrom,
- against the **Insured** and alleging an **incident**. A **claim** does not include a **circumstance**.

**CLASS 1 PRODUCT RECALL**

**Class 1 product recall** means removal or correction of an **insured product** by the **Insured Entity**, where the **Insured Entity**, the **United States Food and Drug Administration** or any foreign equivalent has determined that the **insured product** poses a situation in which there is a reasonable probability that the use of or exposure to such **insured product** will cause serious adverse health consequences or death.

A **Class 1 product recall** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

**CLASS 1 PRODUCT RECALL EXPENSES**

**Class 1 product recall expenses** means reasonable and necessary expenses incurred:

- A. in connection with **insured products** that have been physically relinquished to others and manufactured, processed, packaged, handled, distributed, or sold by the **Insured Entity**;
- B. with the Insurer's prior written consent;
- C. as a result of a **Class 1 product recall**; and
- D. for:
  - 1. any communication costs incurred to announce the withdrawal, including but not limited to:
    - a. telephone, radio, television, and internet announcements; and
    - b. production costs of the announcements, such as printing costs, stationary, envelopes and postage;
  - 2. transporting **insured product** from any purchaser, distributor or user, to locations designated by the **Insured Entity**;
  - 3. transporting the **Insured Entity's employees** to any purchaser, distributor or user in order to effectuate

reasonable and necessary on-site repairs due to a **Class 1 product recall**;

4. remunerating the **Insured Entity's employees** for overtime to perform the actions in 1., 2., or 3. above, and, if necessary, the cost to hire and pay additional persons other than its regular **employees** to perform these actions;
5. properly disposing of **insured product**, including packaging that cannot be reused; or
6. renting temporary locations used to store **insured product**.

However, **Class 1 product recall expenses** do not include **mitigation expenses** or **medical expenses**.

#### **CLINICAL TRIAL**

**Clinical trial** means an organized study, test or written protocol that uses human subjects to establish the effectiveness, bioequivalence or safety of **insured products**.

#### **CLINICAL TRIAL CONSULTANT**

**Clinical trial consultant** means any medical intern, resident, technician, nurse, physician or other medical professional, who provides advice to a **clinical trial investigator**.

#### **CLINICAL TRIAL CONSULTANT SERVICES**

**Clinical trial consultant services** mean professional advice or demonstration of procedures performed by a **clinical trial investigator** in connection with a **clinical trial** as outlined in the written protocol of such **clinical trial**.

#### **CLINICAL TRIAL INVESTIGATOR**

**Clinical trial investigator** mean the individuals who provide services in the **clinical trial** testing of **insured products** as outlined in the written protocol of such **clinical trial**. **Clinical trial investigators** do not include human test subjects in the **clinical trial**.

#### **CONTRACT RESEARCH ORGANIZATION**

**Contract research organization** means any entity that provides **professional services** in connection with, or that organizes or runs **clinical trials**.

#### **COVERAGE PART**

**Coverage part** means only those coverage parts designated as included in the Declarations.

#### **COVERAGE RELATIONSHIP**

**Coverage relationship** means that period of time beginning on the effective date and time of the first policy issued by the Insurer to the **First Named Insured** of which this policy is a renewal in a consecutive series of renewals and the cancellation or nonrenewal of the last such consecutive renewal policy issued by the Insurer to the **First Named Insured**, where there has been no gap in coverage.

#### **DAMAGES**

**Damages** mean judgments, awards and settlements, provided any settlement is made with the Insurer's prior written consent. **Damages** do not include:

- A. fees, costs and expenses (including **mitigation expenses**) paid or incurred or charged by the **Insured**, no matter whether claimed as restitution of specific funds, forfeiture, financial loss, set-off or otherwise, and injuries that are a consequence of any of the foregoing;
- B. civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, statute, regulation or court rule;
- C. the multiplied portion of multiplied awards imposed pursuant to any statute or regulation requiring such awards;

- D. injunctive or declaratory relief;
- E. any amount that is not insurable under any applicable law;
- F. or any amounts for which an **Insured** is liable due to an act or omission in knowing violation of any written contract or agreement; or
- G. plaintiff's attorney fees associated with any of the above.

Notwithstanding paragraph **E.** above, **damages** shall include, subject always to this policy's other terms, conditions and limitations, punitive and exemplary damages. Enforceability of this paragraph shall be governed by such applicable law that most favors coverage for such punitive or exemplary damages.

### **DEFENSE COSTS**

**Defense costs** mean:

- A. fees charged by attorneys designated by the Insurer or by the **Insured** with the Insurer's prior written consent;
- B. all other reasonable and necessary fees, costs and expenses resulting from the investigation, adjustment, defense and appeal of a covered **claim** if incurred by the Insurer, or by the **Insured** with the Insurer's prior written consent, including, but not limited to, premiums for any appeal bond, attachment bond or similar bond but without any obligation of the Insurer to apply for or furnish any such bond;
- C. prejudgment interest awarded against the **Insured Entity** on that part of a judgment the Insurer pays. If the Insurer makes an offer to pay the applicable limit of liability, will not pay any prejudgment interest based on that period of time after such offer; or
- D. interest on the full amount of a judgment that accrues after entry of the judgment and before the Insurer has paid, offered to pay or deposited in court the part of the judgment that is within the applicable limit of liability.

However, **defense costs** do not include:

- 1. salaries, loss of earnings or other remuneration by or to any **Insured**;
- 2. fees and expenses of independent adjusters engaged by the Insurer or salaries of the Insurer's officials or **employees**, other than fees and expenses charged by the Insurer's employed attorneys who may be designated to represent the **Insured** with the **Insured's** consent; or
- 3. mitigation expenses.

### **DOMESTIC PARTNER**

**Domestic partner** means any person qualifying as such under any federal, state or local laws or under the **Insured Entity's** employee benefit plans.

### **EMPLOYEE**

**Employee** means any person whose work or service is directed and controlled by the **Insured Entity**. It includes a leased worker, a volunteer and a temporary worker.

### **EXECUTIVE OFFICER**

**Executive officer** means a person holding any of the officer positions created by the **Insured Entity's** charter, constitution, by-laws or any other similar governing document and its in-house general counsel, corporate risk manager and any **employee** who is responsible for its insurance or claim reporting.

### **EXTENDED REPORTING PERIOD**

**Extended reporting period** means:

- A. with respect to the **Products-Work Hazard Coverage**, the period of time after the end of the **policy period** for the reporting of **claims** to the Insurer that are made against the **Insured** during the applicable **extended reporting period** arising out of an **occurrence** causing **bodily injury** or **property damage**, which injury or damage took place on or after any applicable Retroactive Date and prior to the end of the **policy period**, or arising out of an offense giving rise to **personal and advertising injury**, which offense took place on or after any applicable Retroactive Date and prior to the end of the **policy period**;
- B. with respect to the **Professional Services Coverage**, the period of time after the end of the **policy period** for reporting **claims** to the Insurer that are made against an **Insured** during the applicable **extended reporting period** arising out of **wrongful acts** that took place on or after any applicable Retroactive Date and prior to the end of the **policy period**.

#### **FIRST NAMED INSURED**

**First Named Insured** means the entity first listed as a **Named Insured** in the Declarations.

#### **FORCE MAJEURE**

**Force majeure** means the following unforeseen circumstances if and to the extent they prevent the **Insured Entity** from completing **insured product** or **insured work**: fire; flood; earthquake; epidemic; epizootic; other natural or man-caused calamities; military operations; decisions of governmental authorities; war or civil insurrection.

#### **HAZARDOUS PROPERTIES**

**Hazardous properties** include radioactive, toxic or explosive properties.

#### **IMPAIRED PROPERTY**

**Impaired property** means tangible property, other than **insured product** or **insured work**, that cannot be used or is less useful because:

- A. it incorporates **insured product** or **insured work** that is known or thought to be defective, deficient, inadequate or dangerous; or
- B. the **Insured Entity** has failed to fulfill the terms of a contract or agreement;

if such property can be restored to use by:

1. the repair, replacement, adjustment or removal of **insured product** or **insured work**; or
2. the **Insured Entity's** fulfilling of the terms of the contract or agreement.

#### **INCIDENT**

**Incident** means a **wrongful act**, an **occurrence**, or an offense giving rise to **personal and advertising injury**.

#### **INSTITUTIONAL REVIEW BOARD**

**Institutional review board** means a board, committee (including an ethics committee) panel or similar group designated, directed or requested by a person or organization to review or approve **clinical trials**.

#### **INSURED**

**Insured** means the **Insured Entity** and:

- A. any individual who was, is or becomes the **Insured Entity's** officer, director, member or manager (of a limited liability company), or partner but:
1. with respect to **products-work hazard claims**, solely with respect to the conduct of the **Insured Entity's** business; or
  2. with respect to **professional liability claims**, solely with respect to **professional services** rendered on the **Insured Entity's** behalf.

- B. the **Insured Entity's** stockholders, but only with respect to their liability as stockholders.
- C. the **Insured Entity's employees**, but:
  - 1. with respect to **products-work hazard claims**, only for acts within the scope of their employment or while performing duties related to the conduct of the **Insured Entity's** business; or
  - 2. with respect to **professional liability claims**, solely with respect to **professional services** rendered to others on the **Insured Entity's** behalf.

However, none of these **employees** is an **Insured** for:

a. **bodily injury or personal and advertising injury:**

- i. to the **Insured Entity**, or to its directors, officers, members or managers, partners, or to a co-**employee** while such injured person is either in the course of his or her employment or performing duties related to the conduct of the **Insured Entity's** business;
- ii. to the spouse, **domestic partner**, child, parent, brother or sister of such injured person as a consequence of paragraph a. i. above; or
- iii. for which there is any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury described in paragraphs a. i. or ii. above.

Voluntary participation as a human test subject in a **clinical trial** will not be deemed to be within the scope of employment or performance of duties as described in paragraph a. i. above.

b. **property damage** to property:

- i. owned, occupied or used; or
- ii. rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose;

by the **Insured Entity**, any of its **employees**, any partner or member (if the **Insured Entity** is a partnership or joint venture), or any member (if the **Insured Entity** is a limited liability company).

- D. any person (other than the **Insured Entity's employee**), or any organization while acting as the **Insured Entity's** real estate manager.
- E. **contract research organizations, medical or biotechnology advisors, clinical trial consultants, institutional review boards and clinical trial investigators** (other than the **Insured Entity** or its **employees**). However, no such person or organization is an **Insured** with respect to:
  - 1. any representation or warranty unauthorized by the **Insured Entity**;
  - 2. any physical or chemical change in **insured product** made intentionally by such person without the **Insured Entity's** consent; or
  - 3. such person or organization's rendering or failing to render **professional services** or advice, unless:
    - a. the injury or **damages** arises directly out of the use of **insured products** or **insured work**; and
    - b. the **professional service** or advice is within the scope of a **clinical trial** and is in accordance with written **clinical trial** protocol; and
    - c. the injury or **damages** do not arise out of such person or organization's willful violation of any law or regulation relating to the conduct of a **clinical trial**; and
    - d. the injury or **damages** arise out of the assumption of liability in a contract or agreement.
- F. **medical sales consultants**. However, no such person or organization is an **Insured** with respect to:
  - 1. any representation or warranty unauthorized by the **Insured Entity**;



2. any physical or chemical change in **insured product** made intentionally by such person without its consent;
  3. such person or organization's rendering or failing to render **professional services**; or
  4. such person or organization's rendering or failing to render advice, unless the injury or damage arises directly out of the use of **insured products**.
- G. persons or organizations who are vendors of **insured products**, but they are **Insureds** only with respect to their liability for **damages** resulting from the distribution or sale of **insured products** in the regular course of their business. However, no such person or organization is an **Insured** with respect to:
1. any representation or warranty unauthorized by the **Insured Entity**;
  2. any physical or chemical change in **insured product** made intentionally by the vendor;
  3. repackaging, unless unpacked solely for the purpose of inspection, demonstration, or testing, or the substitution of parts under instruction from the manufacturer and then repacked in the original container;
  4. failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business in connection with the distribution or sale of **insured products**;
  5. demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of **insured products**; or
  6. such vendor's rendering or failing to render **professional services**.
- Further, no person or organization from whom the **Insured Entity** has acquired **insured products**, or any container, ingredient or part entering into, accompanying or containing **insured products**, is an **Insured** under this provision.
- H. any other person or organization to whom or to which the **Insured Entity** is obligated by virtue of a written contract, agreement or permit to provide such insurance as afforded by this policy, but only with respect to liability arising out of **insured product** or **insured work** performed by the **Insured Entity** or on its behalf for that **Insured**. However, this provision does not apply:
1. unless the written contract or agreement has been executed, or the permit has been issued, prior to the **bodily injury, property damage, personal and advertising injury** or any other injury. The contract or agreement will be considered executed when the **Insured's** performance begins, or when it is signed, whichever happens first; or
  2. to any person or organization:
    - a. for **bodily injury, property damage, personal and advertising injury** or any other injury arising out of the **Insured Entity's** sole negligence; or
    - b. included as an **Insured** by an endorsement issued by the Insurer and made a part of this policy.

### **INSURED CONTRACT**

**Insured contract** means that part of any written contract or agreement pertaining to the **Insured Entity's** operations or facilities under which the **Insured Entity** assumes the tort liability of another to pay **damages** because of **bodily injury** or **property damage** to a third person or organization, provided such contract or agreement is made prior to the **bodily injury, property damage** or such other injury. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

### **INSURED ENTITY**

**Insured Entity** means any **Named Insured** and any **subsidiary** or any **newly acquired subsidiary**.

**INSURED PRODUCT**

**Insured product** means any goods or products:

- A. manufactured, developed, designed, created, or tested;
- B. sold, leased, licensed, rented, handled, marketed, distributed to others; or
- C. disposed of;

by the **Insured Entity** or others on the **Insured Entity's** behalf, including but not limited to:

- 1. **biological products, pharmaceutical drugs, medical devices, nutraceuticals**; or
- 2. products that are used, or are intended for use in **clinical trials**, health care or the providing of **professional services**; or
- 3. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.

**Insured product** includes:

- a. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of **insured product**; and
- b. the providing of or failure to provide warnings or instructions.

**INSURED WORK**

**Insured work** means:

- A. work performed by the **Insured Entity** or on its behalf solely in connection with **insured product** or solely in connection with its **clinical trials**, including, but not limited to testing, review, installation, maintenance, or repair of **insured product** or in connection with its **clinical trials**; and
- B. materials, parts or equipment furnished in connection with such work, operations or services.

**Insured work** includes:

- 1. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of **insured work**; and
- 2. the providing of or failure to provide warnings or instructions.

**LOADING OR UNLOADING**

**Loading or unloading** means the handling of property:

- A. after it is moved from the place where it is accepted for movement into or onto an aircraft, watercraft or **automobile**;
- B. while it is in or on an aircraft, watercraft or **automobile**; or
- C. while it is being moved from an aircraft, watercraft or **automobile** to the place where it is finally delivered.

However, **loading or unloading** does not include the movement of property by means of a mechanical device, other than a hand truck, that is not attached to the aircraft, watercraft or **automobile**.

**MANAGEMENT CONTROL**

**Management control** means:

- A. owning interests representing more than 50% of the voting, appointment or designation power for the selection of a majority of: the Board of Directors of a corporation; the management committee members of a joint venture; the managing or general partners of a partnership, or the members of the management board of a limited liability company; or



- B. having the right, pursuant to the **First Named Insured's** by-laws, charter, operating agreement, Partnership Agreement or similar documents, to elect, appoint or designate:
1. a majority of: the Board of Directors of a corporation; the management committee of a joint venture; or the members of the management board of a limited liability company, or
  2. the general partners of a limited partnership or one or more managing partners of a partnership other than a limited partnership.

#### **MEDICAL DEVICE**

**Medical device** means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory that is:

- A. subject to United States Food and Drug Administration regulation, Health Canada regulation or the equivalent of such regulations in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans; or
- C. intended to affect the structure or any function of the human body,

that does not achieve its primary intended purposes through chemical or biological action within or upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

However, **medical device** does not include any **pharmaceutical drug, biological product, nutraceutical** or food.

#### **MEDICAL EXPENSES**

**Medical expenses** means reasonable expense for necessary:

- A. first aid administered at the time of an accident;
- B. medical, surgical, x-ray and dental services, including prosthetic devices; and
- C. ambulance, hospital, professional nursing and funeral services.

#### **MEDICAL OR BIOTECHNOLOGY ADVISORS**

**Medical or biotechnology advisors** means an entity or individuals, other than the **Insured Entity** or its **employees**, who are serving, or have served as the **Insured Entity's** advisor or consultant in a review of the design or development of **insured products**.

#### **MEDICAL SALES CONSULTANT**

**Medical sales consultant** means an entity or individuals (other than the **Insured Entity** or its **employees**) providing advice or demonstrating procedures in connection with the sale or distribution of **insured products** provided that such consultant does not render any direct patient care or **medical services**.

#### **MEDICAL SERVICES**

**Medical services** mean dental, medical, mental, nursing, surgical, x-ray or other similar service performed by a medical intern, resident, technician, nurse, physician or other medical professional, and the furnishing of food, beverages, medications or appliances in connection with such services, and the postmortem handling of human bodies.

#### **MITIGATION EXPENSES**

**Mitigation expenses** means reasonable and necessary fees, costs and expenses incurred by the **Insured Entity** in the **Insured Entity's** efforts to minimize potential **damages** for which the **Insured Entity** might become liable due to a **claim** or **circumstance**. **Mitigation expenses** do not include fees, costs or expenses incurred to comply with

any governmental or regulatory requirement, **class 1 product recall expenses** or **medical expenses**. **Mitigation expenses** do not include **damages** or **defense costs**.

### **MOBILE EQUIPMENT**

**Mobile equipment** means any of the following types of land vehicles, including any attached machinery or equipment:

- A. bulldozers, farm machinery, forklifts and other vehicles designed for use principally off public roads;
- B. vehicles maintained for use solely on or next to premises the **Insured Entity** owns or rents;
- C. vehicles that travel on crawler treads;
- D. vehicles, whether self-propelled or not, maintained primarily to provide mobility to permanently mounted:
  - 1. power cranes, shovels, loaders, diggers or drills; or
  - 2. road construction or resurfacing equipment such as graders, scrapers or rollers;
- E. vehicles not described in **A.**, **B.**, **C.**, or **D.** above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
  - 1. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
  - 2. cherry pickers and similar devices used to raise or lower workers;
- F. vehicles not described in **A.**, **B.**, **C.**, or **D.** above maintained primarily for purposes other than the transportation of persons or cargo.

However, self-propelled vehicles with the following types of permanently attached equipment are not **mobile equipment** but will be considered **automobiles**:

- 1. equipment designed primarily for:
  - a. snow removal;
  - b. road maintenance, but not construction or resurfacing; or
  - c. street cleaning;
- 2. cherry pickers and similar devices mounted on **automobile** or truck chassis and used to raise or lower workers; and
- 3. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

However, **mobile equipment** does not include any land vehicles that are subject to a compulsory or financial responsibility law or other motor vehicle insurance law in the state where it is licensed or principally garaged. Land vehicles subject to a compulsory or financial responsibility law or other motor vehicle insurance law are considered **automobiles**.

### **NAMED INSURED**

**Named Insured** means any entity listed as such in the Declarations.

### **NEWLY ACQUIRED SUBSIDIARY**

**Newly acquired subsidiary** means any entity, newly formed or acquired by the **First Named Insured** or any **subsidiary** during the **policy period** but only for 90 days after such formation or acquisition. In order for coverage to continue beyond such 90 day period, the Insurer must have specifically agreed in writing to add such entity as a **subsidiary** to the policy by endorsement specifying the terms and conditions of its coverage.

**NUCLEAR FACILITY**

**Nuclear facility** means:

- A. any **nuclear reactor**;
- B. any equipment or device designed or used for: separating the isotopes of uranium or plutonium; processing or utilizing **spent fuel**; or handling, processing or packaging **nuclear waste**;
- C. any equipment or device used for the processing, fabricating or alloying of special **nuclear material** if at any time the total amount of such material in the custody of any **Insured** at the premises where such equipment is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof; or 250 grams of uranium 235;
- D. any structure, basin, excavation, premises or place prepared or used for the storage or disposal of **nuclear waste**;

and includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations.

**NUCLEAR MATERIAL**

**Nuclear material** means **source material**, **special nuclear material**, or **by-product material**.

**NUCLEAR REACTOR**

**Nuclear reactor** means an apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material.

**NUCLEAR WASTE**

**Nuclear waste** means waste material:

- A. containing **by-product material** other than the tailings or waste produced by the extraction or concentration of uranium or thorium from ore processed primarily for its **source material** content; and
- B. resulting from the operation by any person or organization of a **nuclear facility** included within paragraphs 1. and 2. of the definition of **nuclear facility**;

used for such operations.

**NUTRACEUTICAL**

**Nutraceutical** means a dietary supplement as defined by the Natural Health Products Regulations, the Food and Drug Act or the United States Dietary Supplement Health and Education Act, whether intended for ingestion or topical application. However, **nutraceutical** does not include any **pharmaceutical drug**, **biological product** or **medical device**.

**OCCURRENCE**

**Occurrence** means an accident, including continuous or repeated exposure to the same general harmful conditions. An **occurrence** will be deemed to have occurred on the earliest date:

- A. **insured product** or **insured work** giving rise to such **claim** was first ingested, implanted, applied or otherwise used;
- B. a **claim** is made alleging **bodily injury** or **property damage** resulting from **insured product** or **insured work**;
- C. a professional medical opinion is rendered that provides a basis for a **claim** under the coverage provided;
- D. **medical expenses** are incurred as a result of **bodily injury**;
- E. death occurs as a result of exposure to **insured product** or **insured work**;
- F. removal or replacement of **insured product**; or

G. an advisory memorandum, class 1 product recall or boxed warning is issued.

#### **PERSONAL AND ADVERTISING INJURY**

**Personal and advertising injury** means injury, including consequential **bodily injury**, arising out of one or more of the following offenses:

- A. false arrest, detention or imprisonment;
- B. malicious prosecution or abuse of process;
- C. wrongful eviction from, wrongful entry into, or the invasion of the right of private occupancy of a room, dwelling or premises that a person occupies committed by or on behalf of its owner, landlord or lessor;
- D. oral or written publication, in any manner, of material that slanders or libels a person or organization or disparages a person's or organization's goods, products or services;
- E. oral or written publication, in any manner, of material that violates a person's right of privacy;
- F. the use of another's advertising idea in the **Insured Entity's advertisement**; or
- G. infringing upon another's copyright, trade dress or slogan in the **Insured Entity's advertisement**.

#### **PHARMACEUTICAL DRUGS**

**Pharmaceutical drugs** mean a synthetic or natural chemical;

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary or any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure of any function of the human body; or
- C. as a component of any product described in paragraph A. or B. above.

However, **pharmaceutical drug** does not include any **biological product, medical device, nutraceutical** or food.

#### **POLICY PERIOD**

**Policy period** means the period of time shown in the Declarations of this policy or as amended by endorsement or cancellation.

#### **POLLUTANTS**

**Pollutants** mean any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

#### **POTENTIAL CLAIM**

**Potential claim** means:

- A. with respect to the **Products-Work Hazard Coverage**, **bodily injury** or **property damage** arising out of an **occurrence**, or rising out of an offense giving rise to **personal and advertising injury**, that any **executive officer** has reason to believe would give rise to a **claim**;
- B. with respect to the **Professional Services Coverage**, an act, error or omission in the rendering of **professional services** that any **executive officer** has reason to believe would give rise to a **claim**.

#### **PRODUCTS-WORK HAZARD**

**Products-work hazard** means:

- A. **bodily injury** or **property damage** arising out of **insured product** or **insured work**; or

**B. personal and advertising injury** but solely to the extent such **personal and advertising injury** arises out of the **Insured Entity's clinical trials**.

However, **products-work hazard** does not include **bodily injury** or **property damage** arising out of:

1. the transportation of property, unless the **bodily injury** or **property damage** arises out of a condition in or on a vehicle created by the **loading or unloading** of it; or
2. the existence of tools, uninstalled equipment, or abandoned or unused materials.

#### **PRODUCTS-WORK HAZARD CLAIM**

**Products-work hazard claim** means a **claim** alleging a **products-work hazard**.

#### **PROFESSIONAL LIABILITY CLAIM**

**Professional liability claim** means a **claim** alleging a **wrongful act** in the rendering of, or the failure to render, **professional services** but solely to the extent such **claim** alleges injury other than **bodily injury, property damage** or **personal and advertising injury**.

#### **PROFESSIONAL SERVICES**

**Professional services** mean those services performed by the **Insured Entity**, or by any other **Insured** on its behalf, for a fee or other remuneration, provided such services are specified in a written contract or agreement for the performance of **professional services** between the **Insured Entity** and its client, which contract was entered into prior to the date of the **wrongful act** giving rise to the **claim** and after the **retroactive date**.

**Professional services** also include:

- A. services incidental to those services specified in such written contract or agreement which incidental services must be done to fulfill the contract and are agreed to by the **Insured Entity** orally or in writing after the execution of the written contract or agreement and prior to the date of the **wrongful act** giving rise to the **claim**; and
- B. **clinical trial consultant services**.

However, **professional services** do not include **medical services**.

#### **PROPERTY DAMAGE**

**Property damage** means:

- A. physical injury to tangible property, including the loss of use thereof. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- B. loss of use of tangible property that has not been physically injured or destroyed. All such loss of use shall be deemed to occur at the time of the **occurrence** that caused it.

#### **RELATED CLAIMS**

**Related claims** means all **claims**:

- A. arising out of the same **wrongful act** or **related wrongful acts**; or
- B. arising out of the same **occurrence** or the same **related occurrences**; or
- C. arising out of the same offense or the same **related offense**.

#### **RELATED OCCURRENCE**

**Related occurrence** is an **occurrence** giving rise to **bodily injury** or **property damage** which **bodily injury** or **property damage** is attributable directly, indirectly or allegedly to the same, actual or alleged event, condition, cause, defect, hazard, advice or decision in the design, formulation, manufacturing, distribution, sale, testing, use, operation, maintenance, repair or replacement of **insured product** or **insured work**. Such **related occurrence** exists regardless of:

- A. when or where such **bodily injury** or **property damage** occurs; or
- B. the number of such **bodily injuries** or **property damage**.

**RELATED OFFENSE**

**Related offense** means all offenses giving rise to **personal and advertising injury** that are logically or causally connected by any common fact, **circumstance**, situation, transaction or event.

**RELATED WRONGFUL ACTS**

**Related wrongful acts** mean all acts or omissions in the rendering of or failure to render **professional services** that are logically or causally connected by any common fact, **circumstance**, situation, transaction, event, advice or decision.

**SOURCE MATERIAL, SPECIAL NUCLEAR MATERIAL AND BY-PRODUCT MATERIAL**

**Source material, special nuclear material and by-product material** have the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof.

**SPENT FUEL**

**Spent fuel** means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a **nuclear reactor**.

**SUBSIDIARY**

**Subsidiary** means any entity in which the **First Named Insured**, directly or indirectly, had **management control** on the inception date of this policy. On the date during the **policy period** that the **First Named Insured** ceases to have such **management control** of such entity, such entity shall cease to be a **subsidiary** under the terms of this policy. In such event, coverage will be provided to such **subsidiary** under the policy but only with respect to **incidents** that occur prior to such date in accordance with all other terms and conditions of this policy. No coverage will be afforded under the policy with respect to **claims** made against such **subsidiary** based on any **incident** that occurred on or subsequent to such date.

**TAKEOVER**

**Takeover** means:

- A. the acquisition by another entity or person, or group of entities or persons acting in concert, of:
  - 1. the ownership or control of voting stock of the **First Named Insured** resulting in such entity, person or group owning or controlling more than 50% of the voting stock of the **First Named Insured**; or
  - 2. assets of the **First Named Insured** resulting in such entity, person or group owning more than 50% of the total consolidated assets of the **First Named Insured** as of the date of the **First Named Insured's** most recent audited consolidated financial statement prior to such acquisition;
- B. the merger of the **First Named Insured** into another entity such that the **First Named Insured** is not the surviving entity; or
- C. the consolidation of the **First Named Insured** with another entity.

**WRONGFUL ACT**

**Wrongful act** means any actual or alleged negligent act, error or omission in the rendering of **professional services** by any **Insured** on the **Insured Entity's** behalf.