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The regulation at the universal and European level regarding nuclear safety and radiation protection of human health and the environment

TREBALL DE FI DE GRAU

Dret

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Curs: 2019/2020

A totes les persones que m'han donat suport i m'han estat ajudant al llarg de l'elaboració d'aquest treball.

En especial, m'agradaria donar les gràcies a Ferran Pons per acceptar totes les meves propostes i ajudar-me a realitzar el treball, al professor Jaume Munich per la seva implicació i els seus coneixements, i a la meva família i les meves amistats per animar-me a tirar endavant un projecte com aquest.

ABSTRACT

Nuclear safety and radiation protection of human health and the environment is going to be the focus of the current work. Nuclear installations, as well as the radioactive waste produced in the nuclear fuel cycle, are dangerous to people, animals and plants. This research aims to study how humans and the environment have been protected from the dangers arising from ionizing radiation, as well as the establishment of safety measures in nuclear facilities. In this way, it has been analysed the regulation adopted at the universal and European level regarding nuclear safety and radiation protection of both humans and environment. At the universal level, we will see the Stockholm and Rio Declarations regarding the environment, and then the IAEA Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel and Radioactive Waste Management as binding instruments, and the IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste and the evolution of both ICRP and IAEA guidelines regarding the environment as the soft law instruments to deal with radiation protection, followed by other organizations relating nuclear energy. At the EU/EURATOM level, we have focus mainly in Directive 2009/71 relating to nuclear safety amended by Directive 2014/87, Directive 2011/70 relating to the management of radioactive waste and Directive 2013/59 laying down basic safety standards for protection against the dangers from ionizing radiation.

ABBREVIATIONS

CNS	IAEA Convention on Nuclear Safety
ECJ	Court of Justice of the European Union
EU	European Union
EURATOM	European Atomic Energy Agency
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICJ	International Court of Justice
ILO	International Labour Organization
OECD	Organization for Economic Co-operation and Development
RAPs	Reference Animals and Plants
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
UN	United Nations
UNGA	United Nations General Assembly
UNEP	United Nations Environment Programme
WHO	World Health Organization

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I. INTRODUCTION.

This research is about the safety of nuclear installations and the radiation produced from nuclear energy, focusing specifically in the effects on human health and the environment. The reason we have choose this topic is due to a personal interest in the energy sector, as well as ignorance of the damages caused by nuclear energy and the legislation applicable to them.

Nuclear energy provides about 14% of the world's electricity from about 440 powers reactors[1]. Since its discovery in the 1940s, nuclear energy advantages and disadvantages has made this alternative energy source one of the most controversial on the market nowadays. In less than a century of existence, we have witnessed devastating catastrophes caused by nuclear energy, from the use of the "atomic bomb" in Hiroshima and Nagasaki to accidents in nuclear power plants such as *Chernobyl*. All these situations, so different from each other, raised in us the question of how it could protect people and the environment from radiation, as well as ensure the safety of nuclear installations.

For many years, the law has largely ignored the obvious connection between energy production and consumption (energy law) and nature (environmental law). Although nowadays the connection has been acknowledged, for the purpose of our work it is important to highlight the differences between both laws.

In short, environmental law and energy law have different aims. For energy law, the economic development; for environmental law, the conservation of resources and protection of public health[2]. Energy law ensures that there are abundant supplies at a reasonable price[3], while environmental law attempts to protect people

[1] WORLD NUCLEAR ASSOCIATION, *Nuclear Power in the World Today*, available at https://www.world-nuclear.org/information-library/current-and-future-generation/nuclear-power-in-the-world-today.aspx, [Accessed on 28/04/2020].
[2] LINCOLN L, D., "Alternative Energy and the Energy-Environment Disconnect", *Idaho Law Review*, 46, 2010, p. 473-480.
[3] TOMAIN, J. & CUDAHY, R., "Energy Law in a Nutshell", *Energy Law Journal*", 32, 2011, p. 631.

and ecosystems from the most immediate and severe harms and reduces the risk of threats to public health and the environment[4].

Even though all energy production is based on natural resources, and thus, imposes numerous environmental impacts, there is no special relationship between energy law and environmental law[5]. Our work will be based on environmental law, leaving aside all the economic aspects and focusing only on the damages produced by nuclear energy to the human beings and to the environment.

The methodology that we will use to find answer to our questions will be a combination of legal sciences with other, such as energy and health sciences, and with other disciplines as sociology. However, it is important to point out that our approach will be characterized by the predominance of the legal analysis. In this way, the other disciplines will only provide additional interpretative support for the legal focus and they will be useful to understand the scientific base of the regulations.

In base of this methodology, we will analyse the normative regarding nuclear safety and the protection of both human beings and the environment from radiation. First, we will see the problem and the general aspects of nuclear energy, such as the concept of radiation and the importance of securing the safety of nuclear installations. Secondly, we will focus in the effort of the international community to deal with the problem, with binding and non-binding regulation. Finally, we will get our attention on the European Level.

The final objective of our work is get our doubts solved, but also that people who read it may get more concern about how radiation from nuclear energy affects the human body, and the need to protect the environment from it too.

[4] See DRIESEN, D. & ADLER, W., *Environmental law: a conceptual and pragmatic approach,* Wolters Kluwer Law & Business, 2016, p. 239–241.

[5] WILDERMUTH, A. J, "The Next Step: The Integration of Energy Law and Environmental Law ", *Utah Environmental Law Review,* 31, 2011, p. 382.

II. GENERAL ASPECTS RELATED TO NUCLEAR ENERGY.

A. Nuclear energy as a substitute for fossil fuels.

The discovery and exploitation of new sources of energy has been central to human progress from the early struggle for biological survival to today's technological world. The first step was learning to control fire, with wood or other biomass as the fuel. This was followed by the harnessing of wind for ships and windmills, the use of waterpower from rivers, and the exploitation of chemical energy from the burning of coal, oil, and natural gas. Nuclear energy, which first emerged in the middle of the 20th century, is the latest energy source to be used on a large scale[6].

For about a century, the dominant energy sources in the industrialized world have been fossil fuels (coal, oil, and natural gas), prevailing now in most of the developing world as well. This energy sources are finite; thus, they will be eventually consumed, and they affect negatively to the global climate change. Since the beginning of the industrial era, and because of the combustion of fossil fuels, there has been a growth of CO_2 emissions that has contribute to the increase of the Earth's temperature[7].

The challenge in energy policy is to reduce CO_2 emissions and the world's dependence on oil while satisfying a substantially increased demand for energy. A possible solution for that challenge is the use of sustainable energy.

Sustainable energy can be defined as energy produced and used in ways that support human development over the long term, in all its social, economic and environmental dimensions[8]. Although sustainable development is susceptible to different definitions, the most commonly accepted is the one of the Brundtland Commission on Environment and Development. In its 1987 Report, *Our Common Future*, stated that sustainable development is the "development that meets the

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[6] BODANSKY, D, *Nuclear energy: principles, practices, and prospects*, Springer Science & Business Media, 2007, p. 1-6.
[7] Other greenhouse gases include methane, chlorofluorocarbons and nitrous oxide.
[8] KURUKULASURIYA, L, & ROBINSON, N. A, (Eds.), *Training manual on international environmental law*, UNEP/Earthprint, 2006, p. 341.

needs of the present without compromising the ability of future generations to meet their own needs*"*[9].

The *Brundtland Report* introduced the concept of sustainability and placed strong emphasis on the importance of energy generation and use as part of this crucial concept. The Report considered energy to be a major feature of sustainability, and defined "public health, recognizing the safety risk posed by use of certain energy types*"*[10] as a key element. The Report also identifies "the risks of nuclear radiation where nuclear energy is used and particularly the problem of nuclear waste" as one of the current environmental problems as a result of unsustainable practices in energy use and production.

On September 25, 2015, the UN General Assembly (UNGA) adopted the 2030 Agenda for Sustainable Development[11], an action plan for people, the planet and prosperity, which is also intended to strengthen universal peace and access to justice. The Agenda proposes 17 Goals with 169 objectives of an integrated and indivisible nature that cover the economic, social and environmental spheres[12]. This new strategy will govern global development programs for the next 15 years.

Of the 17 goals, and for the development of our work, it is important to highlight goal 3 regarding good health and well-being, goal 7 on affordable and clean energy, and goals 13, 14 and 15, regarding climate action, life below water and life on land, respectively. As we will see *infra*, radioactivity emitted by nuclear energy is detrimental to health, both human and animal, as well as damaging the environment, thus goals 3, 13, 14 and 15 would be under the scope of our research. Furthermore, the creation of nuclear energy, as well as the research for renewable energies, would be within the scope of goal 7[13].

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[9] As we will see in the next chapter, the parameters of sustainable development are clarified in Agenda 21 and the Rio Declaration, both adopted at UNCED.

[10] BRUNDTLAND, G. H., World Commission on Environment and Development, *Our common future*, Oxford University Press, 1987, p. 142.

[11] UNGA, *Transforming our world: the 2030 Agenda for Sustainable Development*, Doc. A/RES/70/1, of 21st October 2015.

[12] See, amongst others, LEE, B., *et al*, "Transforming our world: implementing the 2030 agenda through sustainable development goal indicators", *Journal of public health policy* 37(1), 2016, p. 13-31; ANDERSON, K., *et al*, "Earth observation in service of the 2030 Agenda for Sustainable Development", *Geo-spatial Information Science*, 20(2), 2017, p. 77-96.

[13] For more information, see https://www.un.org/sustainabledevelopment/ [Accessed 12/05/2020].

B. Nuclear installations and the nuclear fuel cycle.

A nuclear power plant is a facility designed to produce electrical energy. The heart of the plant is the nuclear reactor, where heat is produced through the fission of atomic nuclei. This heat generates steam, spinning a turbine that converts thermal energy into mechanical energy. The turbine, at the same time, spins an alternator that converts mechanical energy into electrical energy.

The nuclear fuel cycle is the series of industrial processes which involve the production of electricity from uranium in nuclear power reactors. It consists of steps in the *front end*, which are the preparation of the fuel, steps in the *service period* in which the fuel is used during reactor operation, and steps in the *back end*, which are necessary to safely manage, contain, and either reprocess or dispose of spent nuclear fuel. If spent fuel is not reprocessed, the fuel cycle is referred to as an "open fuel cycle", and if the spent fuel is reprocessed, as a "closed fuel cycle".

The stages of the nuclear fuel cycle are[14]:

i. **Uranium mining**: Uranium is a common metal that can be found throughout the world. There are three ways to mine it: open pit mines, underground mines and *in situ* leaching where the uranium is leached directly from the ore.

ii. **Uranium milling**: Milling is generally carried out close to a uranium mine. The mined uranium ore is crushed and chemically treated to separate the uranium. The result is called "yellow cake", a yellow powder of uranium oxide (U_3O_8). In yellow cake, the uranium concentration is raised to more than 80%.

iii. **Conversion**: Once the uranium is milled, the "yellow cake" concentrate is shipped to a conversion facility. Natural uranium consists primarily of two isotopes, 99.3% is U-238 and 0'7% is U-235. The fission process by which heat energy is released in a nuclear reactor take place mainly in U-235. To increase the concentration of U-235, uranium must be enriched.

[14] IAEA, *The nuclear fuel cycle, 2011*, available at: https://www.iaea.org/sites/default/files/nfc0811.pdf

Since enrichment happens in gaseous form, "yellow cake" is converted to uranium hexafluoride gas (UF_6), filled into large cylinders where it solidifies and shipped to an enrichment plant.

iv. **Enrichment**: Uranium is enriched in U-235 by introducing the gas in fast-spinning cylinders, where heavier isotopes are pushed out to the cylinder walls. This enrichment increases the proportion of the U-235 isotope.

v. **Fuel fabrication**: The enriched uranium (UF_6) cannot be directly used in reactors, as it does not withstand high temperatures or pressures. It is therefore converted into uranium oxide (UO_2). Fuel pellets are formed by pressing UO_2, which is sintered (baked) at temperatures of over 1400^{o}C to achieve high density and stability. The pellets are packed in long metal tubes to form fuel rods, which are grouped in "fuel assemblies" for introduction into a reactor.

vi. **Electricity generation**: Once the fuel is loaded inside a nuclear reactor, controlled fission can occur. Fission means that the U-235 atoms are split. The splitting release heat energy is used to heat water and produce high pressure steam. The steam turns a turbine connected to a generator, which generates electricity. The fuel is used in the reactor for 3-6 years. About once a year, 25% to 30% of the fuel is unloaded and replaced with fresh fuel.

vii. **Spent fuel storage**: The spent fuel assemblies removed from the reactor are very hot and radioactive. Therefore, the spent fuel is stored under water, which provides both cooling and radiation shielding. After a few years, spent fuel can be transferred to an interim storage facility. This facility can involve either wet storage, where spent fuel is kept in water pools, or dry storage, where spent fuel is kept in casks. Both heat and radioactivity decrease over time. After 40 years in storage, the fuel's radioactivity will be about a thousand times lower than when it was removed from the reactor.

viii. **Reprocessing**: The spent fuel contains uranium (96%), plutonium (1%) and high-level waste products (3%). The uranium, with less than 1% fissile U-235, and the plutonium can be reused. Some countries chemically reprocess usable uranium and plutonium to separate them from unusable waste.

Recovered uranium from reprocessing can be returned to the conversion plant, converted to UF6 and subsequently re-enriched. Recovered plutonium, mixed with uranium, can be used to fabricate mixed oxide fuel (MOX).

ix. **Spent fuel and radioactive waste disposal**: Spent nuclear fuel or high-level radioactive waste can be safely disposed of deep underground, in stable rock formations such as granite, thus eliminating the health risk to people and the environment.

C. Radioactive Waste.

The use of nuclear energy inevitable generates radioactive waste, that is, substances that are no longer used that emit radioactivity and therefore must be treated with care. However, nuclear energy production is not the only responsible of radioactive waste production, as there are other activities (such as medical, military or industrial) that produce also this type of waste.

Regarding the fuel cycle, the main activities that generate radioactive waste are:

i. **Extraction and treatment of uranium minerals.** After extracting the uranium from the originating mineral, the surplus material still contains traces of uranium, in addition to other radioactive elements generated in the disintegration of the uranium

ii. **Nuclear fuel production.** This activity involves various phases of chemical conversion, uranium enrichment and fuel element manufacturing.

iii. **Use of fuel in the reactor.** The fission of fuel is the primarily responsible for the production of radioactive substances. During its process, fission products are generated, and the absorption of neutrons gives rise to numerous trans-uranium elements (all of them radioactive), being plutonium the main one.

iv. **Management of irradiated fuel.** Fuel drawn from the reactor contains more than 95% of the total radioactivity of nuclear waste. The fuel itself, if not reused, is a radioactive waste, but if it is subjected to treatment to recover the fissile material that still contains, it can be considered as a raw material.

Another important source of radioactive waste is the dismantling of the facilities at the end of their life, in order to give the corresponding sites the possibility of a new use.

Although there is no single classification, the criteria underlying the most widely used classification done by the International Atomic Energy Agency (IAEA) are the intensity of radiation emitted and the time at which the level of radiation remains dangerous. In practice, the combination of both criteria (level and duration of radioactive emissions) is useful to indicate the type of treatment, transport and disposal that can be expected for waste.

CLASSES[15]	**DESCRIPTION**
Very short-lived waste (VSLW)	Waste that can be stored for decay over a limited period of up to a few years. This class includes waste containing primarily radionuclides with very short half-lives often used for research and medical purposes.
Very low-level waste (VLLW)	Waste that does not need a high level of containment and isolation and, therefore, is suitable for disposal in near surface landfill type facilities. This class includes soil and rubble with low levels of activity concentration.
Low level waste (LLW)	Waste that is above clearance levels, but with limited amounts of long-lived radionuclides. This waste requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near surface facilities. This class covers a very broad range of waste, from short lived radionuclides with a high level of activity concentration to long lived radionuclides with relatively low levels of activity concentration.

[15] IAEA, "Classification of Radioactive Waste", *IAEA Safety Standards Series,* No. GSG-1, 2009.

Intermediate level waste (ILW)	Waste that requires a greater degree of containment and isolation than the provided by near surface disposal, requiring disposal at greater depths (from ten metres to a few hundred meters). This class covers long lived radionuclides that will not decay to a level of activity concentration from near surface disposals.
High level waste (HLW)	Waste with levels of activity concentrations high enough to generate significant quantities of heat by the radioactive decay process, or waste with large number of long-lived radionuclides that need to be considered in the design of a disposal facility. The generally recognized option for this waste is the disposal in deep and stable geological formations (several hundred metres or more below the surface).

D. The environment.

Before we focus on the protection of the environment, it would be interesting to see how the environment is defined and approached internationally.

Defining the "environment" presents difficulties, as none of the major treaties, declarations, guidelines or code of conducts referred directly to it has done it. Dictionary definitions range from "the air, water, and land in or on which people, animals, and plants live"[16] to "the whole complex of climatic, edaphic and biotic factors that act upon an organism or an ecological community and ultimately

[16] *The Cambridge Dictionary of Philosophy*, 3rd ed., 2015.

determine its from or survival; the aggregate of social or cultural conditions that influence the life of an individual or a community"[17].

As we will see in the next chapter, the Declaration of the 1972 Stockholm Conference on the Human Environment referred in the preamble to the "man's environment", adding that both aspects of the man's environment, the natural and the man-made, "are essential to his well-being and to the enjoyment of basic human rights"[18], while the 1992 Rio Declaration on Environment and Development refers to environmental needs, protection, degradation and so on, but without identifying what these include[19].

One of the few bodies to defined it is the European Commission. In developing an 'Action Programme on the Environment', it defined "environment" as "the combination of elements whose complex inter-relationships make up the settings, the surroundings and the conditions of life of the individual and of society as they are and as they are left*"*[20].

The agreements that defines "environmental effects, impacts or damages" typically include harm to flora, fauna, water, air, soil, landscape, cultural heritage and any interaction between them[21]. Probably the broadest approach is found in the 1992 Framework Convention on Climate Change, which defines in its article 1.1 the concept "adverse effects on the environment" to include

> "changes in the physical environment or biota, resulting from climate change, which have significant deleterious effects on the composition, resilience and productivity of natural and managed ecosystems, or on the operation of natural and managed ecosystems or on the operation of socio-economic systems or human health and welfare".

[17] *Webster's New World Dictionary*, 3rd ed., 1988.
[18] UN, *Declaration on the United Nations Conference on the Human Environment,* Doc. A/CONF.48/14/Rev 1, of 16th June 1972.
[19] UN, *Rio Declaration on Environment and Development,* Doc. A/CONF.151/26/Rev 1, of 12th August 1992.
[20] Council Regulation (EEC) No 1872/84 of 28 June 1984 on Action by the Community Relating to the Environment, *OJ L 176,* 3.7.1984, p. 1-5.
[21] Some examples are the 1992 Convention on the Transboundary Effects of Industrial Accidents and the 1993 Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment.

Another indication of what the term "environment" includes is given by the broad range of issues now addressed by international environmental law, including from the conservation and sustainable use of natural resources and conservation of migratory species to the protection of the oceans and the safeguard of human health and quality of life.

As we will see in the following chapters, it has been difficult to protect the environment from radiation contamination, due to the lack of definition and to the insufficient information on how radiation affects to it. The protection from ionizing radiation has been basically aimed at the protection of human beings, treating the environment as a simple space where humans live together. However, and how we will see *infra*, the environmental concern has increase over the years.

As the International Court of Justice (ICJ) recognizes, "the environment is under daily threat and the use of nuclear weapons could constitute a catastrophe for the environment"[22].

E. Nuclear safety.

In general, we can give a definition of civil nuclear safety (leaving aside the application to military uses). Nuclear safety means the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionizing radiation from nuclear installations (article 3.2 of Directive 2009/71)[23].

Apart from accidents, the release of radioactivity may be due to intentional actions. Although for the study of our work we will focus only on accidents, it is important

[22] ICJ, *Legality of the Threat or Use of Nuclear Weapons,* Advisory Opinion of 8th July 1996, *ICJ Reports 1996*, para. 29.
[23] Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations., *OJ L 172*, 2.7.2009. p. 18-22.

to point out the difference between the concepts of "safety" (regarding accidents) and "security" (against sabotages)[24].

The safety of nuclear facilities depends on the project and its implementation, but also on its management, that is, on the "human factor". As it will be explained *infra*, the *Three Mile Island* and *Chernobyl* accidents have witnessed a series of human errors without which the accident would not have occurred, or at least would have had less serious consequences.

The *Three Mile Island* accident[25] was a meltdown at a nuclear power plant in Middletown, Pennsylvania. The *Three Mile Island* plant had two pressurized water reactors. TMI-1 entered service in 1974 and still operates safely, while TMI-2 was brand new when the accident occurred. At 4 a.m. on March 28th of 1979, a cooling circuit malfunctioned, allowing the primary coolant to overheat. The reactor shut down immediately, and the release valve opened for 10 seconds (allowing enough coolant to escape to reduce pressure and heat). The valve got stuck in the open position, resulting in all the coolant being released. As a result of the coolant escaped, new coolant rushed into the tank, making the engineers think that there was too much coolant and reducing the flow by themselves. The fuel rods overheated, melting the protective coating, which released radioactive material into the coolant. When the steam was released, the radioactive contaminant was discharged into the surrounding area.

Fortunately, the amount of radioactive material released was not enough to harm local food supplies, animals or people. Officially it caused no deaths, but unofficial investigations and lawsuits claimed there were above-average rates of cancer and birth defects in the surrounding area.

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[24] DE PAOLI, L., *La Energía Nuclear. Elementos para un debate,* Alianza Editorial, 2011, p. 78-80.
[25] WORLD NUCLEAR ASSOCIATION. *Three Mile Island Accident*, available at: https://www.world-nuclear.org/information-library/safety-and-security/safety-of-plants/three-mile-island-accident.aspx, [Accessed on 14/04/2020].

The accident at the *Chernobyl* nuclear power plant[26] on April 26th, 1986, was a major humanitarian catastrophe of the twentieth century. At 1:23 a.m., the reactor 4 of the facility exploded and ruptured the reactor vessel. The workers wanted to find out if the turbines alone could keep the cooling safety system running, and since they couldn't turn the reactor off, they powered it down to 25% of the normal power. To conduct the test at this low level, they switched off the safety system, but things didn't went as planned. The reactor power fell to less than 1% of the normal power, and when they started powering it back up to the desired level, a power surge occurred, ending in the rupture of the reactor. The explosion blew off the 1000-ton sealing cap, and temperatures rose above 2000ºC. The heat melted the fuel rods and subsequently caught on fire the graphite covering them. It burned for nine days, steadily releasing radiation.

When the fourth reactor exploded, there were over 1000 radioactive elements released into the atmosphere. Two workers died immediately from the explosion, and 28 firemen and emergency clean-up workers died in the first three months from radiation. At least 20.000 children got thyroid cancer from the radiation, around 200.000 people were relocated, and the rate of suicides, alcoholism and depression increased in the population around the accident's area[27]. The accident created also a radioactive cloud that spread over Europe in the following months, contaminating principally food sources.

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[26] IAEA, *Frequently Asked Chernobyl Questions*, available at: https://www.iaea.org/newscenter/focus/chernobyl/faqs, [Accessed 14/04/2020].

[27] IAEA, *Chernobyl's Legacy: Health, Environmental and Socio-economic impacts*, available at: https://www.iaea.org/sites/default/files/chernobyl.pdf, [Accessed 14/04/2020].

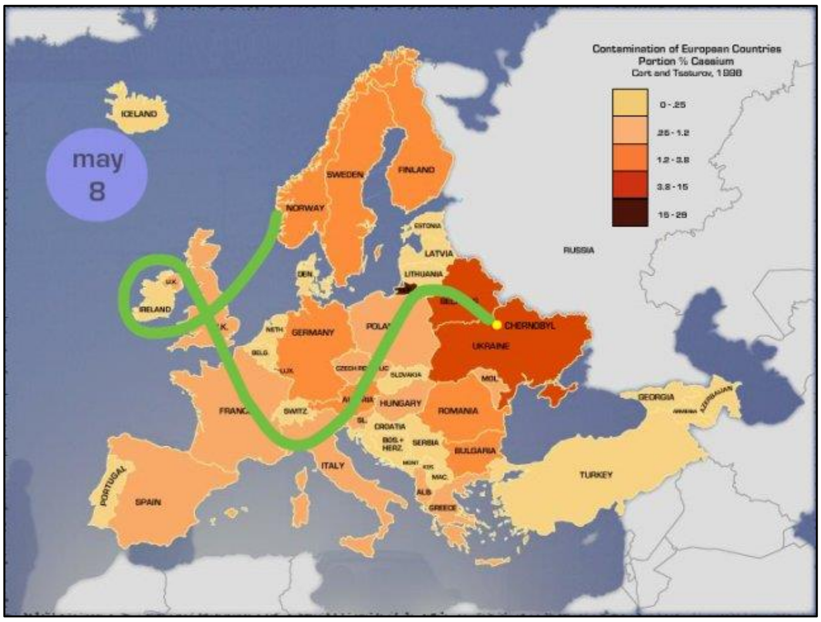

Fig. 1. A green animation of the radioactive cloud's path across Europe showing *levels of caesium contamination in each country*[28].

The *Fukushima* accident is different from the two explained before, because the "human factor" was not the cause of the disaster. On March 11, 2011, a 9.1 magnitude earthquake occurred 370 km northeast of Tokyo. 30 minutes later, a 40 metres high tsunami pummelled Japan's north-eastern shoreline [29] . The consequences were catastrophic, but to make things worse, the tsunami damaged the Fukushima Daiichi nuclear power plant, creating radioactive leaks. The tsunami disabled the cooling system at three of the six reactors, and the cores melted within 72 hours. At firsts, engineers couldn't stop the radioactive leakage, and when they did it, it took months to halt the emissions completely.

[28] Created by Kate Chanba, Matt Forrest, Vanessa Knoppke-Wetzel, and Andrew Wilson of the University of Wisconsin-Madison. The project shows the lasting impact of the 1986 nuclear accident on Ukraine and the rest of Europe.
[29] DE PAOLI, *op cit.*, 120-131.

Radiation showed up in local milk, vegetables and briefly appeared in Tokyo's drinking water[30]. Radioactive materials continued to leak into the Pacific Ocean, raising to levels 7.500 times higher than the legal limit[31].

In terms of the "human factor", what experience has shown is that, in order to spread and preserve the safety of nuclear installations, two things are important: the rapid exchange of information between all managers of similar plants and the evaluation and inspection of the personnel, and not just the facility, by a supervisory authority[32].

Leaving aside human errors, nuclear installations are potentially hazardous and create possibly risks to human health and the environment for the simple fact of existing. Also, as these accidents show, modern nuclear technology creates unavoidable risks for all States, whether or not they choose to use this form of energy.

F. Radiation protection.

Radioactivity is the result of the transformation of matter and the transfer of energy from one point in space to another. Despite being everywhere and being a manifestation of the universe, radioactivity was discovered in 1896 by Wilhelm Röntgen. This discovery contributed to the understanding of the structure of the atom. Until the end of the 19th century, the atom was basically thought to be stable and indivisible. However, between the end of the 19th century and the beginning of the 20th, an atom model similar to the solar system was affirmed, in which in the centre is the nucleus, and in it are two types of nucleons with almost equal masses: neutrons, without electric charge, and protons, positively charged.

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[30] TOKYO METROPOLITAN INSTITUTE OF PUBLIC HEALTH, *Levels of radioactive materials in tap water obtained every day, 2011 fiscal year*, available at: http://monitoring.tokyo-eiken.go.jp/en/mon_water_data_2011.html, [Accessed 14/04/2020].

[31] "Fukushima radioactivity hit 7'5M times legal limit", *The Guardian*, available at: https://www.theguardian.com/world/2011/apr/05/fukushima-radioactiviy-above-legal-limit, [Accessed 14/04/2020].

[32] DE PAOLI, *op cit.*, 90-91.

Just a few months later of the discovery of radioactivity, X-ray dermatitis was observed in the USA. Radioactivity was used by military field hospitals as early as 1897, although the number of X-ray injuries escalated during the Great War when primitive mobile X-ray equipment was used in the field[33]. Just 1 year after Röntgen discovery of X-rays, the engineer Wolfram Fuchs gave what is generally recognised as the first protection advice[34]:

- Make the exposure as short as possible.
- Do not stand within 12 inches (30 cm) of the X-ray tube; and
- Coat the skin with Vaseline (a petroleum jelly) and leave an extra layer on the most exposed area.

In the early 1920s, radiation protection regulations were prepared in several countries, but it was not until 1925 that the first International Congress of Radiology (ICR) took place and considered establishing international protection standards.

The radiation energy can be enough to tear an electron from a molecule or an atom, or to break a molecular bond. If the cell receiving the impact is a cell in the human body, it can be damaged or even die. The energy of the absorbed radioactivity is called "dose" and is measured in greys (Gy), which corresponds to a unit of absorbed energy (measured in joules, J) and a unit of mass (in kg). The higher the dose, the greater the energy absorbed and the greater the consequences.

As for damages to the human body, what matters is not so much the radiation that the source emits. Instead, the relevant factor is the radiation that is absorbed by the affected one. Furthermore, the biological effects depend not only on the amount of radiation absorbed, but also on the type of radiation, the organ affected and the relationship between the dose and the duration of application. For all this, what the sanitary protection takes into account is the "equivalent dose", whose unit of measurement is the sievert (Sv), which is equal to the Gy multiplied by a quality factor that goes from 1 to 20 according to the type of radiation. Gy and Sv are two

[33] ICRP, *Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations*, ICRP Publication 109, 2009, p. 77.
[34] FUCHS, W., "Simple recommendations on how to avoid radiation harm", *Western Electrician*, 12, 1896.

fairly large units, so it is common to use submultiples (for example, the millisievert: mSv).[35]

The International Commission on Radiological Protection (ICRP) classifies the health effects of radiation exposure in two categories. The first one is the deterministic effects, resulting in the death or malfunction of the cells of a tissue as a consequence of very high exposures. In contrast, the second one is the stochastic effects, derived from low doses and manifesting themselves with a notable delay (years or decades after irradiation).

To protect populations from radiation, the ICRP has developed a series of principles and recommendations that form the basis of national regulations. In particular, it has indicated the following admissible dose limits for sources of artificial radioactivity[36]:

i. For the general public, an average of 1 mSv of effective dose per year, not including medical and occupational exposures.
ii. For occupational exposure (employees in sectors where the use of radioisotopes is expected), the limit is 50 mSv in a single year with a maximum of 100 mSv in a consecutive five-year period.
iii. If emergency situations occur, a maximum of 100 mSv per year (dose above which deterministic effects begin).

[35] DE PAOLI., *op cit.*, 44-52.
[36] ICRP, *The 2007 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103, 2007.

III. REGULATION OF NUCLEAR SAFETY AND RADIATION PROTECTION AT THE UNIVERSAL LEVEL.

Before we start studying the universal regulations, it is important to explain the concept of soft law and hard law, and the role they play in the topic of our research.

The soft law regulations[37] represent to the international environmental law an instrument to project principles and legal opinions that, without being binding and obligatory, creates the guideline of the international rules. In fact, soft law regulations, very common in environmental law, mean an alteration in the scheme of the sources of international law[38].

The amount of soft law regulations has not blocked the creation of hard law regulations[39], implementing mandatory rules to establish binding obligations and real control, as a real *ius cogens*[40].

First we will see two UN Declarations concerning the environment, followed by two IAEA Conventions that are the first global treaties to commit States to control the risks of nuclear energy for environmental objectives and to protect human health from nuclear damages. Then we will study an IAEA Code of Practice applied to the movement of radioactive waste and the evolution of both IAEA and ICRP guidelines and recommendations to seek a real protection of the environment.

Lastly, we will see the Organisation for Economic Co-operation and Development (OECD) and the International Labour Organization (ILO) and its regulations regarding nuclear energy and radiation protection, respectively.

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[37] See, amongst others, GRUCHALLA-WESIERSKI, T., "A framework for understanding 'soft law'", *McGill Law Journal*, 30 (1), 1984-1985, p. 37-88; BIERZANEK, R., "Some Remarks on 'soft' International Law", *Polish Yearbook of International Law*, 17, 1988, p. 21-40; HILLGENBERG H., "A Fresh Look at Soft Law*", EJIL*, 10 (3), 1999, p. 499-517; SHELTON, D. (ed.), *Commitment and compliance; the role of non-binding norms in the international legal system*, OUP, 2003.

[38] CHINKIN, Ch. M., "The Challenge of soft law: development and change in international law*", International & Comparative Law Quarterly*, 38 (4), 1989, p. 850-866.

[39] JUSTE, J., *Derecho Internacional del medio ambiente,* McGraw-Hill, 1999, p. 39; see also JUSTE, J., CASTILLO, M., *La protección del medio ambiente en el ámbito international y en la Unión Europea,* Tirant lo Blanch, 2014.

[40] *Ibid,* 48.

A. General regulations on the environment relevant for nuclear energy.

1. Declaration of the United Nations on the human environment (Stockholm Declaration of 1972).

The Stockholm Conference, held from 5 to 16 June of 1972, was the first important step at the international level to raise awareness of environmental problems, and the importance to protect and enhance the human environment.

In this Conference three instruments with recommended character were adopted: the *Stockholm Declaration*, the Action Plan for the Environment and the UNEP. We will focus on the *Stockholm Declaration*, because it is the one that contributes to the future regulation of our item. The *Stockholm Declaration* proclaims 7 statements and set up 26 principles about the environment, but we will concentrate in those that are relevant for the nuclear energy and radioactive pollution.

Thereby, principle 1 sets the man in the middle of the environment and reflects the anthropocentric perspective of environmental law. This principle also introduces for the first time the "human right to the environment", although the Declaration does indeed refer to the human's "fundamental right to […] adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being", and brings to us the responsibility of protecting our surrounding environment, as it states that the man "bears a solemn responsibility to protect and improve the environment for present and future generations". This protection is also established in principle 4, where the Declaration states that "Man has a special responsibility to safeguard and wisely manage the heritage of wildlife and its habitat".

Principles 6 and 7 formulate the obligation to end the discharges of toxic substances that damage the environment, plus the duty to prevent pollution of the seas. In this way, pollution from radioactive substances can be interpreted under those two principles.

Principle 18 sets the environmental protection target in science and technology, being directly applicable to the creation of nuclear energy and the risks that involves.

Another relevant provision is in principle 21, which establishes that States have the sovereign right to exploit their own resources but the obligation to ensure that those activities do not cause damage to the environment of other States or of areas beyond their national jurisdiction. The ICJ has address this topic, affirming that

> "The existence of the general obligation of States to ensure that activities within their jurisdiction and control respect the environment of other States or of areas beyond national control is now part of the corpus of international law relating to the environment"[41].

From a legal perspective, the most relevant provisions are in principles 22 and 24[42]. Principle 24 sets the base for the international co-operation in aim to protect the environment, establishing that "all countries should be engaged in [...] the protection and improvement of the human environment", calling for that international co-operation "to effectively control, prevent, reduce and eliminate adverse environmental effects resulting from activities conducted in all spheres". Principle 22 appoints that "States shall cooperate to develop further the international law regarding liability and compensation for the victims of pollution and other environmental damage" [43].

Finally, principle 26 made a straight reference to our topic, stating that *"Man and his environment must be spared the effects of nuclear weapons"* and expressing that "*States must strive to reach prompt agreement [...] on the elimination and complete destruction of such weapons"*[44].

Therefore, and regarding its non-binding status, the *Stockholm Declaration* established the base of future binding regulation, as for example the ones that we will see *infra*.

[41] ICJ, *Legality of the Threat or Use of Nuclear Weapons,* Advisory Opinion of 8th July 1996, *ICJ Reports 1996*, para. 29.
[42] SANDS, P., *et al.*, *Principles of International Environmental Law*, Cambridge, 2012, p. 32.
[43] STEPHENS, T., *International courts and sustainable development*, Environmental Discourses in Legal Institutions, 2012, p. 64-89.
[44] De italic is ours.

2. *Declaration of the United Nations on environment and development (Rio Declaration of 1992).*

The *Rio Declaration* on environment and development, amongst other instruments, was adopted as a result of the Rio Conference on Environment and Development (or Earth Summit) that was set up from 1 to 15 June 1992. This declaration contains 27 principles that contributes for the achievement of sustainable development and to protect the integrity of the global environmental and developmental system (Annex I).

The *Rio Declaration* is clearer than the *Stockholm Declaration*, since for example, in its principle 1 establishes that human beings “are at the centre of concerns for sustainable development” and that they “are entitled to a healthy and productive life in harmony with nature” [45]. Principle 2 establishes the responsibility of States to protect the environment, as we saw in principle 21 of the *Stockholm Declaration*, but adds the responsibility for the citizens at principle 10, emphasizing that “environmental issues are best handled with the participation of all concerned citizens”, and the prior duty to States to “facilitate and encourage public awareness and participation by making information widely available”.

The heart of the *Rio Declaration* is in principles 3 and 4, establishing the obligation to protect the environment for present and future generations (principle 3) and the integration of environmental protection “in order to achieve sustainable development” (principle 4).

As we saw in the *Stockholm Declaration*, international co-operation between States is the core of environmental protection. Thereby, principle 12 establishes that

> “States should co-operate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation”,

[45] SANDS, *op cit.,* 34-39.

principle 13 calls for the creation of common liability and compensation setting up that "States shall also cooperate […] for adverse effects of environmental damage", and principle 14 encourage this idea of cooperation as it sets up that

> "States should effectively co-operate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health".

In addition, the *Rio Declaration* introduces the polluter pays principle[46] in principle 16, and principle 19 sets the responsibility to States to notify and inform other potentially affected States on activities that may have a "significant adverse transboundary environmental effect", effects that are commonly seen in all the threats provoked by nuclear and radioactive damages and that have end in the creation of conventions such as the Convention on Early Notification of a Nuclear Accident[47] or the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency[48].

It is important to notice that the soft law essence is reflected using the term "shall" in sixteen of the twenty-seven principles. Thus, it is clear that the *Rio Declaration* is more accurate than the Stockholm one[49].

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[46] The "polluter pays" principle establishes that the responsible for producing pollution has to pay for the damage done to the natural environment.
[47] IAEA Convention on Early Notification of a Nuclear Accident of 26th of September of 1986, and in force from 27th of October of 1986.
[48] IAEA Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency of 26th of September of 1986, and in force from 26th of February of 1987.
[49] DE SADELEER, N., *Environmental Principles: From Political Slogans to Legal Rules*, OUP, 2002, p. 159-163.

B. Firsts steps in regulation of nuclear safety and radiation protection.

The environmental law is one of the youngest fields of law, for this reason the regulation of nuclear safety and radiation protection of human health and the environment is relatively recent.

In the early days of nuclear energy, it was widely believed that the benefits outweighed the risks and could be shared by all[50]. This optimistic view was reflected in international policy, in specific with the creation of the IAEA in 1956. This organization was created with the object of encouraging and facilitating the spread of nuclear power (IAEA Statute, article III.1 to 4) and was assumed that nuclear energy would contribute to 'peace, health and prosperity' throughout the world (article II).

Article III.A.6 of the IAEA Statute authorizes the Agency to adopt 'standards' of safety for the purposes of protecting health and minimizing danger to life and property from exposure to radiation, in collaboration with other UN agencies (such as WHO, ILO, or the OECD). The term 'standards' includes regulations, rules, requirements, code of practice and guides, but those adopted by the IAEA can be classified in three basic categories. 'Safety fundamentals' provide a statement of basic objectives, concepts and principles for ensuring safety in general terms. 'Safety requirements' lay down detailed regulatory standards which must be satisfied in order to ensure the safety of specific types of installation or activity. 'Safety guides' are recommendations, based on international experience, and usually deal with ways and means to ensure the observance of safety requirements'[51].

IAEA standards cover a wide amount of areas, amongst them radiation protection, and are regularly updated in the light of current technical advice from the agency's own independent specialist advisory bodies and the ICRP, whose recommendations seek to limit the damage of radiation on human health and the environment to an 'acceptable' level. The Board of Governors first approved radiation protection

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[50] Agreed Declaration on Atomic Energy, (United States, Canada, UK), Washington, 1945, 1, *UNTS* 123.
[51] BIRNIE, P., *et al.*, *International Law & the Environment,* OUP, 2009, p. 492-499.

requirements in 1962 and has revised periodically thereafter[52]. Regulations on the safe transport of nuclear material was adopted first in 1961, and a Code of Practice on the International Transboundary Movement of Radioactive Waste was added in 1990 in order to exclude such material from the Basel Convention on Transboundary Movements of Hazardous Waste[53].

Nothing in the IAEA Statute confers any binding force on health and safety standards[54]. But in 1968, the policy of non-proliferation and the powers of the IAEA were strengthened by the Nuclear Non-Proliferation Treaty[55]. Three nuclear powers and a large majority of UN member acknowledge "the devastation that would be visited upon all mankind by a nuclear war" and agreed to prevent the spread of nuclear weapons.

The existence of a threat to health and the environment, however, was recognized in the 1963 Partial Test Ban Treaty, which banned nuclear weapons tests in the atmosphere, outer space, and under water[56]. Although the treaty banned nuclear tests, France and China continued testing their nuclear weapons, prompting condemnation at the *Stockholm Conference* in 1972[57] and at the UN[58].

The popularity of nuclear power as an answer to the oil crisis in the 1970s brought long-term health and the environmental consequences to the forefront of international concern, but nuclear reactor accidents at *Three Mile Island* in the United States and *Chernobyl* in the former Soviet Union showed how serious were risks for health, agriculture, and the environment posed by nuclear power. Spreading contamination over a wide area of Eastern and Western Europe, the accident at *Chernobyl* in 1986, like the sinking of the *Torrey Canyon* oil tanker in

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[52] See last version IAEA, FAO, I., OECD, N., PAHO, U., & WHO, R. P, "International Basic Safety Standards for Protection Against Ionizing Radiation, *IAEA Safety Standards Series*, No. 115., 1996.
[53] Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal of 22 March 1989, article 1(3).
[54] SZASZ, P. C., *The law and practices of the International Atomic Energy Agency*, IAEA, 1970.
[55] MÜLLER, H., *et al.*, (eds), *Nuclear Non-Proliferation and Global Order*, OUP, 1994.
[56] Treaty Banning Nuclear Weapons Test in the Atmosphere, in Outer Space and Under Water of 5th August 1963.
[57] UN, *Declaration on the United Nations Conference on the Human Environment*, *op cit.*, principle 26.
[58] UNGA, Resolution 3078 (XXVIII), *Urgent need for suspension of nuclear and thermonuclear tests*, of 6th December 1973.

1967[59], revealed the limitations of international policy for containing catastrophic risks and some of the true costs of nuclear power.

Chernobyl cast doubt on the adequacy of national and international regulation of nuclear facilities and showed how limited were the powers of IAEA[60], giving more importance to the interest of neighbouring States in the siting of nuclear power plants, the opportunities for consultation on issues of safety and the right to prompt notification of potentially harmful accidents[61].

For the first time, and after the dangers of nuclear energy were seen, an international body, the Council of Europe, was prepared to describe nuclear energy as 'potentially dangerous', to recommend a cessation on construction of new facilities and the closure of those that did not meet international standards[62].

Although the *Chernobyl* accident brought to the table the necessity of an international regulatory regime for the safe use of nuclear energy, it was not until the adoption of the Conventions on Nuclear Safety and the Safety of Spent Fuel and Radioactive Waste Management in 1994 and 1997, respectively, where binding minimum standards for environmental protection from nuclear risks where established. As we will see *infra*, these treaties codified much of the customary international law relating to nuclear activities and gave legal force to IAEA safety principles and standards, representing an important stage in the evolution of international regulation and supervision of nuclear power and its waste.

All the conventions, treaties, guidelines, and recommendations that had been mentioned were based basically in the protection of human health from nuclear materials and the effects of ionizing radiation in their lives. As we will see later, the ICRP and the IAEA have worked together to analyse, determine and prevent the effects of ionizing radiation on the environment, establishing guidelines and recommendations and remarking the importance of the conservation and preservation of the environment.

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[59] See GIL, C., *et al., The wreck of the Torrey Canyon,* David & Charles, 1967.
[60] CAMERON, P., *et al* (eds), *Nuclear Energy Law After Chernobyl,* Graham & Trotman, 1988.
[61] BIRNIE, *op cit.,* 491-492.
[62] PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE, *Recommendation 1068 on Nuclear accidents,* of 25 January 1988.

C. Regulation of nuclear safety and radiation protection at IAEA level.

1. IAEA Convention on Nuclear Safety (CNS).

The CNS[63] aims at increasing the safety of civil nuclear power plants world-wide, and it has been ratified by 88 States. The principal obligations embodied in the Convention are based largely on IAEA's own safety fundamentals for nuclear installations[64]. Due to that, the Convention has three objectives: to achieve and maintain a high level of nuclear safety worldwide; to establish and maintain effective defences in nuclear installations against potential radiological hazards to protect individuals, society and the environment from the harmful effects of ionizing radiation; and to prevent accidents with radiological consequences and to mitigate such consequences if they occur (article 1). The Convention is applied to the safety of nuclear installations, defined in article 2(i) as

> "any land-based civil nuclear power plant under its jurisdiction including such storage, handling and treatment facilities for radioactive materials as are on the same site and are directly related to the operation of the nuclear power plant".

Although the Convention does take a significant step towards defining the obligation of States operating nuclear installations, it seeks to pursue the objectives by enhancing national measures and international cooperation, rather than by fully internationalizing the regulation and supervision of the nuclear industry[65].

Parties are required to establish a national regulatory body (article 8) and to establish and maintain a legislative and regulatory framework (article 7) to govern the safety of nuclear installations, reaffirming in the Preamble (iii) that "responsibility for nuclear safety rests with the State having jurisdiction over a nuclear installation". In this way, parties are required to take "appropriate steps" to ensure that the safety of nuclear installations is reviewed as soon as possible (article

[63] IAEA Convention on Nuclear Safety of 17th of June of 1994, and in force from 24th of October of 1996.
[64] IAEA, "The Safety of Nuclear Installations", *IAEA Safety Series,* No 110, 1993.
[65] BIRNIE, *op cit.,* 500-503.

6), the quality of the staff is adequate (article 11), the quality assurance programmes are established (article 13), that comprehensive and systematic safety assessments are carried out periodically (article 14), and that emergency plans are prepared (article 16). Amongst this “General Safety Considerations”, we must highlight article 15, being the only one that refers directly to radiation protection, establishing that

> “Each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits”.

In relation to the safety, siting of nuclear installations should be evaluated for setting up the “likely safety impact of a proposed nuclear installation on individuals, society and the environment” (article 17 ii) and design and construction should provide for “several reliable levels and methods of protection against the release of radioactive materials” (article 18 i). Regarding the operation we must highlight section viii of article 19, where with respect to the generation of radioactive waste, it establishes that

> “the generation of radioactive waste resulting from the operation of a nuclear installation is kept to the minimum practicable for the process concerned, both in activity and in volume, and any necessary treatment and storage of spent fuel and waste directly related to the operation and on the same site as that of the nuclear installation take into consideration conditioning and disposal”.

Article 20 provides for the parties to meet periodically to review reports on measures they have taken to implement their international safety obligations, specifying in section 3 that each party “shall have a reasonable opportunity to discuss the reports submitted by other contracting parties and to seek clarification of such reports”. This mechanism is the main innovative and dynamic element of the Convention.

2. IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste.

The IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste was adopted in September 1990 by the IAEA General Conference at its 34th regular session[66] and establishes a set of non-binding principles designed to serve as guidelines[67].

The Code is in conformity with the relevant principles and norms of international law and relies on existing international standards for the safe transport of radioactive material and the physical protection of nuclear material, and the standards for basic nuclear safety and radiation protection and radioactive waste management[68], and is mainly based on the 1989 Basel Convention[69].

Regarding radiation protection, the Code is aware of the potential hazards for both human health and the environment caused by the improper management or disposal of radioactive wastes, takes into account the IAEA's safety principles and recognizes the global role of that organization in that area, amongst nuclear safety and radioactive waste management and disposal (Preamble ii, vi and xi).

Radioactive waste is defined in article 2 as

> "any material that contains or is contaminated with radionuclides at concentrations or radioactivity levels greater than the "exempt quantities" established by the competent authorities[70] and for which no use is foreseen[71]".

[66] IAEA GENERAL CONFERENCE, *Code of Practice on the International Transboundary Movement of Radioactive Waste,* Resolution 530 (XXXIV), of 21st September 1990.
[67] The 1990 Code is a good example of IAEA soft law: most provisions are written in non-mandatory terms, using the world 'should'.
[68] JANKOWITSCH, O., "Code of practice on the international transboundary movement of radioactive waste", *IAEA Bulletin*, 32(4), 1990, p. 28-31.
[69] As it was said before, the Basel Convention does not apply to nuclear waste specifically covered by other international instruments: see article 1(3).
[70] As it is established in Section II, a competent authority is 'an authority designated or otherwise recognised by a government for specific purposes in connection with radiation protection and/or nuclear safety.
[71] Spent fuel which is not intended for disposal is not considered to be radioactive waste.

Despite its non-binding legal character, the Code is more limited in scope than the more stringent approaches set out in the Basel[72] and Bamako[73] Conventions, both international conventions aiming to protect human health and the environment against the adverse effects of the movements of hazardous wastes in the world and in Africa, respectively.

Its “obligations” are so soft that is questionable whether they provide any enforceable guidance[74]: a state should minimise the amount of radioactive waste and take appropriate steps to ensure that radioactive waste within its territory, jurisdiction or control is safely managed and disposed (Section III, paras. 1 and 2).

In contrast to the Code, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management contains more stringent regulation of the transboundary movement of spent nuclear fuel or radioactive waste. Article 27 of the Joint Convention is modelled on the Basel Convention and requires exporting parties to take appropriate steps to ensure that transboundary movement is authorised and takes place only with the prior notification and consent of the state of destination (article 27.1.i).

3. *IAEA Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.*

The Joint Convention[75] is the first legal instrument to address the issue of spent fuel and radioactive waste management safety on a global scale, and it has been ratified by 83 States.

The Convention is based mainly on IAEA’s 1995 Principles of Radioactive Waste Management[76], and has three major objectives, established at article 1: to achieve

[72] 1989 Basel Convention, *op cit.*
[73] Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa of 30 January 1991.
[74] SANDS, *op cit.*, p. 574-575.
[75] IAEA Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5th of September of 1997, and in force from 18th of June of 2001.
[76] IAEA, “Principles of Radioactive Waste Management Safety Fundamentals”, *IAEA Safety Series*, No. 111-F, 1995.

and maintain a high level of safety worldwide in spent fuel and radioactive waste management, to ensure that during all stages of spent fuel and radioactive waste management there are effective defences against potential hazards to protect against harmful effects of ionizing radiation and to prevent accidents. The Convention applies to spent fuel management and to radioactive waste disposal (article 3), but with three exceptions which make it less than comprehensible[77]. It does not cover spent fuel held at reprocessing facilities as part of a reprocessing activity unless the relevant contracting party declares reprocessing to be part of spent fuel management[78], to radioactive waste that contains only naturally occurring radioactive materials and that does not originate from the nuclear fuel cycle, and to spent fuel or radioactive waste within military or defence programmes.

The main provisions of the Convention are similar to those found in the CNS, addressing the safety of spent fuel management (articles 4-10) and of radioactive waste management (articles 11-17) by the design, siting and operation of related facilities, and the establishment of a regulatory framework and independent regulatory body (articles 4-26).

Regarding radiation protection, we must highlight articles 12, 19, 24 and 26. Article 12 (ii) refers to existing facilities and past practices, establishing that "each contracting party shall take the appropriate steps to review the results of past practices in order to determine whether any intervention is needed for reasons of radiation protection", while article 19 (i) establishes that the legislative and regulatory framework shall provide for "the establishment of applicable national safety requirements and regulations for radiation safety". The Joint Convention has also the same kind of control regime as the CNS, although the national reporting requirements are more detailed and potentially onerous (articles 29-37).

Radiation protection in his own strict sense is regulated in article 24, entitled "Operational radiation protection". Whereas the CNS provides only that radiation exposure shall not exceed prescribed *national* dose limits (article 15), article 24 of

[77] BIRNIE, *op cit.*, 503-505.
[78] Due to Indian and Pakistani opposition.

the Joint Convention requires national radiation limits to have “due regard to internationally endorses standards on radiation protection”. This article also classifies the potential affected ones in three different categories: workers and the public, individuals, and the environment.

Then, “radiation exposure of the *workers and the public* caused by the facility shall be kept as low as reasonably achievable, economic and social factors being taken into account”, “no *individual* shall be exposed, in normal situations, to radiation doses which exceed national prescriptions for dose limitation which have due regard to internationally endorsed standards on radiation protection” and “measures are taken to prevent unplanned and uncontrolled releases of radioactive materials into the *environment*”[79]. Section 2 of the same article establishes the same limitation to radiation protection but referred to “discharges”.

Lastly, article 26 (ii) referred to the decommissioning of nuclear facilities establishes that contracting parties “shall ensure that the provisions of article 24 with respect to operational radiation protection […] are applied”.

As it was mentioned *supra*, article 27 gives binding force for the first time to the main provisions of IAEA’s 1990 Code of Practice on the International Transboundary Movement of Radioactive Waste.

4. Evolution of ICRP and IAEA guidelines and recommendations concerning the radiation protection of the environment.

As we can observe from principle 1 of both *Stockholm* and *Rio Declarations*, the environmental law has an anthropocentric point of view, siting the humankind in the focus of interest. However, and over the pass of the years, the ICRP has highlight the importance of the protection of the environment and has study the effects of ionizing radiation on it and the ways to prevent further damages.

[79] The italic is ours.

The first time that the Commission addressed the protection of the environment was in its 1977 Recommendations, establishing that:

> "Although the principal objective of radiation protection is the achievement and maintenance of appropriately safe conditions for activities involving human exposure, the level of safety required for the protection of all human individuals is thought likely to protect other species, although not necessarily individual member of those species. The Commission therefore believes that if man is adequately protected then other living things are also likely to be sufficiently protected"[80].

In 1991, the Commission produced new recommendations, retaining essentially the same position as in the 1977 ones:

> "The Commission believes that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species. At the present time, the Commission concerns itself with mankind's environment only with the regard to the transfer of radionuclides through the environment, since this directly affects the radiological protection of man"[81].

As we can extract from both recommendations, the ICRP's system of protection provided protection for humans. In fact, it is probably true that the human habitat has been afforded a fairly high level of protection through the application of the Commission's system of protection, but the problem stays in demonstrate that the environment is, or will be, adequately protected in different circumstances[82].

[80] ICRP, *Radiation protection in uranium and other mines,* ICRP Publication 24, 1977, para. 14.
[81] ICRP, *1990 Recommendations of the International Commission on Radiological Protection,* ICRP Publication 60, 1991, para. 16.
[82] CLARKE, R., HOLM, L., *Development of ICRP's philosophy on the environment*, ICRP Publication 108, 2008.

For example, there was information about radiation effects on specific animals and plants, but it was never approached as a common “environment”.

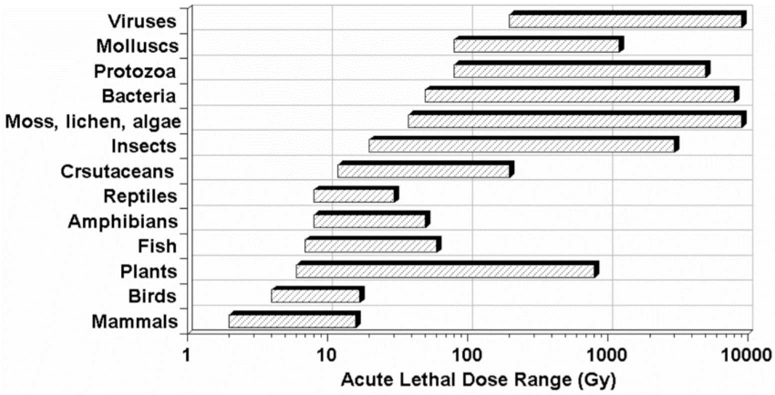

Fig. 2.1. Acute dose ranges that result in 100% mortality in various taxonomic groups. Humans are among the most sensitive mammals, and therefore among the most sensitive organisms[83].

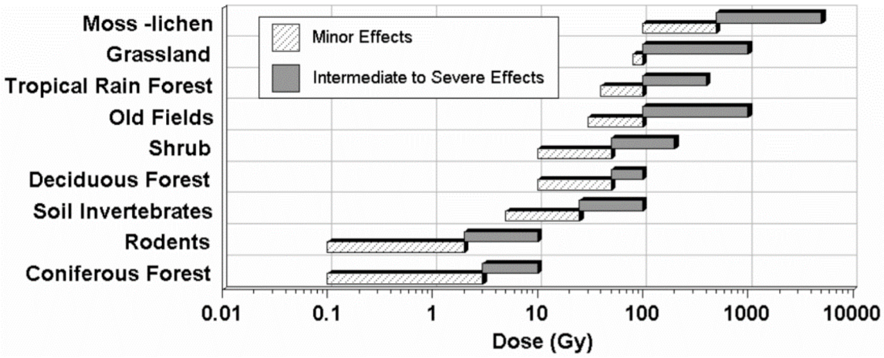

Fig. 2.2. Range of short-term radiation doses (delivered over 5 to 60 d) that produced effects in various plant communities, rodents and soil invertebrates. Minor effects include chromosomal damage, changes in productivity, reproduction and physiology. Intermediate effects include changes in species composition and diversity through selective mortality. Severe effects (massive mortality) begin at the upper range of intermediate effects[84].

[83] WHICKER, F. W., SCHULTZ, V., “Radioecology: Nuclear Energy and the Environment”, *CRC Press*, 1, 1982, p. 147-162.
[84] WHICKER, F. W., FRALEY, L., “Effects of ionizing radiation on terrestrial plant communities”, *Advances in Radiation Biology*, 4, 1974, p. 317-366, and reviewed by Whicker in 1997.

It was not until 2003 in *Publication 91*[85] where the environment was directly protected. *Publication 91* provided a starting point for the Commission's further considerations of how it could provide evidence of protection of the environment, as opposed to relying on the notion that actions to protect humans indirectly provide adequate protection of the environment. In this publication, ICRP stated that:

- A possible future ICRP system addressing environmental assessment and protection would focus on biota, not on the abiotic component of the environment, or on environmental media (soil, air, water, sediment);
- The system should be effect-based so that any reasoning about adequate protection would be derived from firm understanding of harm at different exposure levels; and
- The system should be based on data set for Reference Fauna and Flora [subsequently termed "Reference Animals and Plants" (RAPs)[86]].

In 2005, the ICRP established "Committee 5" in response to the need to provide direct demonstration of environmental protection from radiation. In their first report they developed a small set of RAPs (taking as a model the Reference Man), to serve as a basis to understand and interpret the relations between exposure to radiation and the doses of that exposure. At the same time, the IAEA created the "Coordination Group on Radiation Protection of the Environment" to achieve the same objectives.

In 2006, the IAEA incorporated the concept of "environmental protection" on their own Fundamental Safety Principles. The protection of the environment was established in principle 7, entitled "Protection of present and future generations", where states that the effects of radiation on the environment have been less investigated, than the ones on human health, and that the general intent of the

[85] ICRP, *A framework for assessing the impact of ionising radiation on non-human species*, ICRP Publication 91, 2003.
[86] The definition of a RAP, as subsequently developed by the Commission in *Publication 108* (ICRP, 2008) is 'a hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of family, with defined anatomical, physiological, and life history properties, that can be used for the purposed of relating exposure to dose, and dose to effects, for that type of living organism'.

measures taken are the protection of populations of species different than the human one[87].

One year later the ICRP published its 2007 Recommendations (*Publication 103*) and environmental protection was incorporated as one of the integral elements of the radiation protection system[88], devoting exclusively the eight chapter to the environment. These recommendations effectively extended the system of protection to address that protection to the environment, including flora and fauna, and also explained the basis for the proposed RAPs mentioned before.

In 2009, *Publications 108*[89] *and 114*[90] created an overall framework for protection of the environment in parallel with the protection of humans, but the "lack of relevant data and the nature of the dynamics of wild populations of animals and plants" showed the impossibility to secure the risk and the real effects of radiation exposure on the environment. The concept of RAPs was dealt with in more detail in *Publication 108*, containing information on the assumed biology, dosimetry and available effects database, meanwhile *Publication 114* provided transfer parameters for the set of RAPs.

For the general public, compliance with the relevant numerical values is demonstrated by way of a representative person (Fig. 2.1). As we have seen *supra*, the overall framework developed for protection of the environment has much in parallel with the ones for humans, as illustrated in Fig. 2.2. However, and due to the lack of information already pointed out, is not always possible to identify those who are most likely to be at risk.

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[87] IAEA, FAO, I., OECD, N., PAHO, U., & WHO, R. P., "Fundamental Safety Principles", *IAEA Safety Standards Series*, No. SF-1, 2006.
[88] ICRP, *The 2007 Recommendations …, op cit.*
[89] ICRP, *Environmental protection: the concept and use of Reference Animals and Plants*, ICRP Publication 108, 2009.
[90] ICRP, *Environmental protection: transfer parameters for Reference Animals and Plants*. ICRP Publication 114, 2009.

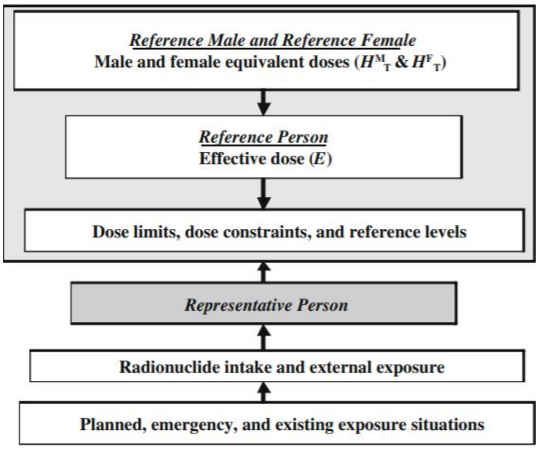

Fig. 3.1. Relationships between various points of reference for protection of the public[91].

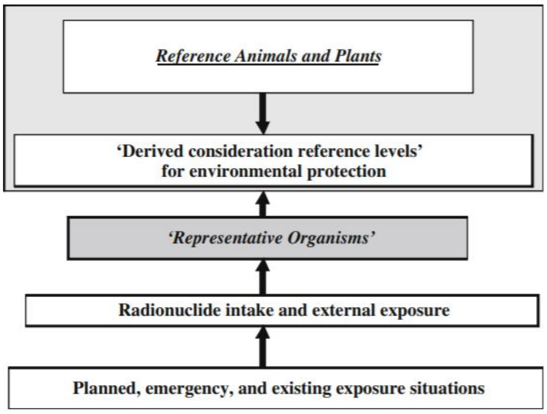

Fig. 3.2. Relationships between various points of reference for protection of the environment[92].

The creation and innovation of the ICRP's point of view of the environment, and the need of its protection, made the IAEA revise in 2011 its "International Basic Radiation Protection Standards" [93] , adding the concept of "environmental protection".

[91] ICRP, *Environmental protection: the concept and use …*, *op cit.*, p. 21.
[92] *Ibid*.
[93] See last version: IAEA, FAO, I., OECD, N., PAHO, U., & WHO, R. P., "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards", *IAEA Safety Standards Series*, No. GSR Part 3, 2014.

In 2014, ICRP's *Publication 124*[94] established a more detailed study of the "different exposure situations" of radiation on the environment. It classifies the exposure on "planned", "emergency" or "existing". Planned exposure are situations "resulting from the operation of deliberately introduced sources", emergency exposure are situations "resulting from a loss of control of a planned source or from any unexpected situation", and existing exposure are situations "resulting from sources that already exist when a decision to control them is taken".

Lastly, in 2018, the IAEA developed a series of safety guides regarding the radiation protection of the public and the environment. It takes as a starting point the three possible exposure situations detailed in *Publication 124* and remarks the importance of treating each type of exposure differently. It also recaps everything that has been said and explained in other publications, remembering that

> "the general intent of the measures taken for purposes of environmental protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms"[95].

Is important to highlight that both institutions are in constant study of the area and are working towards new recommendations, guidelines or standards that will help us to understand better the effects of ionizing radiation on the environment, achieving in the next years a more precise and correct approach to the real damage produced by the radiation.

[94] ICRP, *Protection of the environment under different exposure situations*. ICRP Publication 124, 2014.
[95] IAEA, "Radiation Protection of the Public and the Environment", *IAEA Safety Standards Series*, No. GSG-8, 2018.

D. Other institutions and its regulations regarding nuclear safety and radiation protection.

1. The Organization for Economic Co-operation and Development (OECD).

The OECD[96] is an intergovernmental economic organization, established in 1960 to promote policies designed to achieve in its member countries the highest sustainable economic growth, sound economic expansion in the process of economic development, and the expansion of world trade (Convention on the OECD, article 1). Increasingly, the membership of the OECD extends beyond Europe giving it a global reach[97]: eleven of its thirty-seven members are not european States, with Colombia being the last addition on 28th April 2020.

In 1957 the Nuclear Energy Agency (NEA) was established, and has the mission of

> "assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for the safe, environmentally friendly and economical use of nuclear energy for peaceful purposes"[98].

NEA currently has thirty-three countries from Europe, North America and the Asia-Pacific region, and together they account for approximately 85% of the world's installed nuclear capacity. This institution has become an important forum for cooperation at various levels, for example the harmonization and development of national nuclear law on a consensus basis[99]. In the nuclear field, the organization has similar aims to those of IAEA, but without the safeguard's role. They include encouraging the adoption of common standards dealing with public health and the prevention of accidents[100].

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[96] Formerly the Organization for Economic Co-operation (OEEC).
[97] SANDS, *op cit.*, 77-79.
[98] NEA, *The Strategic Plan of the Nuclear Energy Agency 2017-2022*, available at: https://www.oecd-nea.org/general/about/strategic-plan2017-2022.pdf.
[99] BIRNIE, *op cit.*, 507.
[100] Formerly the European Nuclear Energy Agency (ENEA); Statute, Article 1.

In collaboration with IAEA and other bodies, it has developed standards on radiation protection and waste management, amongst others.

While the OECD Convention does not specify environmental protection among its functions, the organization began to address environmental issues in 1970 following the decision to create an Environment Committee as a subsidiary body to the Executive Committee, which is itself subordinated to the OECD Council.

It is important to highlight that the 1972 OECD Council Recommendation on Guiding Principles Concerning the International Economic Aspects of Environmental Policies was the first international instrument to refer expressly to the polluter pays principle[101], endorsing that principle to allocate the costs of pollution prevention and control measures to encourage rational use of environmental resources and to avoid distortions in the international trade and investment[102].

Since 1972, the OECD Council has adopted a large number of environmental measures and has promulgated a treaty on liability for nuclear damage[103]. These environmental actions have influenced the development of national environmental legislation in the member countries, and have often provided a basis for international standards and regulatory techniques in other regions and at a global level[104].

2. *The International Labour Organization (ILO).*

The purposes of the ILO, established in 1919, include the protection of workers against sickness, disease and injury arising out of employment, and the adoption of humane conditions of labour (ILO Constitution, Preamble)[105]. To this end, the ILO has adopted a number of conventions which set international standards for

[101] SANDS, *op cit.*, 230-231.
[102] OECD, *Recommendation of the Council on Guiding Principles concerning International Economic Aspects of Environmental Policies*, on 26 May 1972.
[103] Convention on Third Party Liability in the Field of Nuclear Energy of 29th July 1960, and Supplementary Convention of 31st January 1963.
[104] SANDS, *op cit.*, 78.
[105] *Ibid*, 73.

environmental conditions in the workplace, including occupational safety and health, as well as numerous non-binding recommendations and guidelines[106].

Beyond the IAEA Safety Standards, the 1960 ILO Convention 115 Concerning the Protection of Workers Against Ionizing Radiations aims to ensure effective protection of workers against ionizing radiations[107].

Although there is no reference to the environment, it is important to highlight this Convention because it has been ratified by 50 States. To protect workers from radiation, the Convention establishes the level of exposure to radiation and maximum permissible doses that they can handle (articles 5, 6.1, 7 and 8), and also provides for warnings to be used to indicate radiation hazards, the instruction of workers on precautions, the monitoring of workers and workplaces, and regular medical examinations (articles 9-12).

[106] For example, see *Fundamental Principles of Occupational Health and Safety*, 2nd ed, 2008; 2009 ILO Code of Practice on Safety and Health in Underground Coal Mines; and 2005 ILO Code of Practice on Safety and Health in Ports.
[107] ILO Radiation Protection Convention 115 of 22nd of June of 1960, and in force from 17th of June of 1962, Article. 3(1).

IV. REGULATION OF NUCLEAR SAFETY AND RADIATION PROTECTION AT THE EUROPEAN LEVEL.

Although we will focus on the regulation at the European level, it is important to highlight that other regions have developed also regulations relating to the topic of our work. In this line, we must point out the already mentioned Bamako Convention on the Ban of the Import and Control of Radioactive Waste into Africa[108], and the Waigani Convention to ban the importation of radioactive waste into the Forum Island countries and to control the transboundary movement of those wastes within the South Pacific Region[109]. As the Basel Convention, they aim to reduce or eliminate transboundary movements of hazardous and radioactive waste into Africa and the Pacific region respectively, to minimize the production of hazardous and toxic wastes and to ensure that disposal of wastes is complemented in an environmentally sound manner[110].

A. Legal framework of EU/EURATOM in environmental matter.

The origins of the European Union (EU) started in 1951 with the European Coal and Steel Community treaty, followed by the European Atomic Energy Community (EURATOM) and the treaty on European Economic Community, both of 1957. But it was not until February of 1986 with the treaty of the European Union Act that the Economic European Community started to be competence in the environmental matter. Nowadays, the EU has an important role in the environmental regulation and its framework is set in the Treaty on European

[108] 1991 Bamako Convention, *op cit*

[109] Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement of Hazardous wastes within the South Pacific Region (known as Waigani Convention), of 16th September 1995.

[110] Environment sound technologies are techniques and technologies capable of reducing environmental damage through processes and materials that generate fewer potentially damaging substances, recover such substances from emissions prior to discharge, or utilize and recycle production residues.

Union (TEU) of 1992 (Maastricht treaty)[111] and the Treaty on the Functioning of the European Union (TFEU) of 2007 (Lisboan treaty)[112].

The last two treaties establish the base of EU on environmental matters, permitting in consequence the regulation about some aspects of nuclear energy.

In one hand, we must highlight article 3.3 of the TEU as it regards that the EU "shall work for the sustainable development of Europe […] and a high level of protection and improvement of the quality of the environment". The protection of the environment is also established in the preamble, as it sets that the EU is determined to reinforce cohesion and environmental protection. Also, it is important to point out that these common policies should be done with the cooperation between the Member States according with article 21.2.d.

In the other hand, the TFEU establishes a more detailed base for the future regulation of environmental matters at the EU level. As it was recognized in article 21.2.d TEU, articles 3.2.e and 153 of the TFEU sets up that the environmental competence is shared between the EU and the Member States. It also establishes the obligation to integrate environmental protection requirements into the EU policies (article 11 TFEU).

According to article 114.4 and 5, Member States could maintain national provisions relating the protection of the environment when there is a major need regarded in article 36 of the treaty (114.4) and "when deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State" (114.5). In both situations, Member States shall notify the Commission of these provisions as well as the grounds for maintaining them. Article 177.2 of the same treaty sets up a "Cohesion Fund" to provide a financial contribution to environmental projects.

[111] Consolidated version of the Treaty on European Union, *OJ C 326*, 26.10.2012, p. 13-390.
[112] Consolidated version of the Treaty on the Functioning of the European Union, *OJ C 326*, 26.10.2012, p. 47-390.

Moreover, the Title XX is dedicated exclusively to the environment. Article 191.1 establishes the objectives that the EU environmental policy has to pursuit in order to protect the environment. These objectives include the preservation, protection and improve of the quality of the environment, the protection of human health and a prudent and rational use of natural resources.

According to article 191.3, the policies of EU must take into account:

i. available scientific and technical data,
ii. environmental conditions in the various regions of the Union,
iii. the potential benefits and costs of action or lack of action,
iv. the economic and social development of the Union as a whole and the balanced development of its regions.

The EU policy on the environment "shall aim at a high level of protection" and "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at a source and that the polluter should pay" (article 191.2). All those policies are taken by the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions (article 192.1).

It is important to highlight that all the protective measures adopted pursuant to article 192 "shall not prevent any Member State from maintaining or introducing more stringent protective measures" (article 193). In those cases, such measures must be compatible with the Treaties and they shall be notified to the Commission.

In addition, the Title XXI is dedicated to the energy. In order to establish the internal market and considering the need to preserve and improve the environment, the EU policy on energy shall aim to "(a) ensure the functioning of the energy market; (b) ensure security of energy supply in the Union; (c) promote energy efficiency and energy saving and the development of new and renewable of energy; and (d) promote the interconnection of energy networks" (article 194.1). The Parliament and the Council, acting in accordance with the ordinary legislative procedure, and after consulting the Economic and Social Committee and the

Committee of the Regions, shall adopt the measures necessary to achieve the objectives set at paragraph 1 (article 194.2.1). Those measures shall not affect the right of a Member State to "determine the conditions for exploiting its energy resources, its choice between different energy sources and the general structure of its energy supply" (article 194.2.2).

The EURATOM Treaty[113] was signed by the European Economic Community Member States in 1957 for the purpose of creating a nuclear common market (Article 2 and Chapter IX). The treaty's objective includes the application of uniform safety standards to protect the health of workers and the general public against radiation. This is established in article 30, which defines the concept "basic standards" to mean: "(a) maximum permissible doses compatible with adequate safety; (b) maximum permissible levels of exposure and contamination and (c) the fundamental principles governing the health surveillance of workers".

In matters of radiation protection, and according to articles 33 and 38 of the EURATOM Treaty, it is the responsibility of the Commission to establish the Uniform Safety Standards for radiation protection. Once the Commission establishes these standards, the Council of the European Communities, with the aid of European Parliament, adopts them[114].

As we will see *infra*, the first Directive regarding these safety standards was adopted in 1959[115], being subsequently modified over the years to reflect and incorporate scientific developments in the area of radiation protection and the

[113] The European Atomic Energy Community (EURATOM) had the original purpose of creating a specialist market for nuclear power in Europe, but over the years its scope has been considerably increased to cover a large variety of areas associated with nuclear energy and ionizing radiation. The EURATOM bodies are the same than the EU ones, so we will study them together. Although having the same bodies, the EURATOM is legally distinct from the EU and it is the only remaining community organization that is independent of the EU and therefore outside the regulatory control of the European Parliament.

[114] MOLODSTOVA, E., "Nuclear Energy and Environmental Protection: Responses of International Law", *Pace Environmental Law Review*, 12, 185, 1994, p. 224.

[115] Directive of 2 February 1959, laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations, *OJ C 11*, 20.2.1959, p. 221-259.

recommendations of the ICRP. It was not until the latest version in 2014 where the "environment" was referred directly[116].

Nevertheless, the EURATOM and European Communities law fall short of creating an obligation for Member States to submit all their nuclear installations to independent environmental or safety assessment by the Commission, as it remains as national responsibilities. Despite its apparent advantages, the EURATOM Treaty has neither supplanted nor extended the IAEA Statute as a basis for regulating nuclear environmental risks[117].

B. First steps of EU/EURATOM regulation in nuclear safety and radiation protection.

Since the creation of the EURATOM, the legislation about the safety of nuclear installations and the management of waste was orientated to the radiological protection of the public, the society and the professional workers upon article 30 of the EURATOM Treaty.

In this way, we can see how various regulations and directives were created until 2003, denoting the lack of harmonization in the European Community's legislation. Although *infra* we will study the three most currently relevant Directives in the field of ionizing radiation protection, it is important to highlight Directives 92/3/Euratom [118] and Council Regulation (Euratom) No 1493/93 [119] about shipments of radioactive substances, and Directives 89/618/Euratom [120] ,

[116] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, *OJ L 13*, 17.1.2014, p. 1–73.

[117] BIRNIE, *op cit.,* 505-506.

[118] Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community, *OJ L 35,* 12.2.1992, p. 24-28.

[119] Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States, *OJ L 148,* 19.6.1993, p. 1-7.

[120] Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, *OJ L 357*, 7.12.1989, p. 31-34.

90/641/Euratom[121], 97/43/Euratom[122], 2003/122/Euratom[123] and 96/29/Euratom[124] regarding health, information and protection from radioactive radiation.

Despite all those last directives regarding health problems were repealed by the Council Directive 2013/59/Euratom[125] in 2014, we must point out that Directive 96/29 regarding radiation protection was the most complete development to date of Chapter 3 of Title II of the Euratom Treaty, establishing uniform safety standards for the protection of the health of workers and the general public against the dangers of ionizing radiation. This served as the base for the nuclear safety proposals that we will see later, since the specific basic rules of safety that we will study afterwards were complementary to the ones introduced in Directive 96/29.

Also it is important to highlight the Council Resolution of 22 July 1975 on the technical problems of nuclear safety[126], as it establishes that nuclear safety problems affecting health and the environment should be considered in a community level, recognizing that "nuclear safety problems extend beyond the frontiers not only of Member States but of the Community as a whole" and that it was necessary for the Commission "to act as a catalyst for initiatives to be taken on a broader international plane".

[121] Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risks of ionizing radiation during their activities in controlled areas, *OJ L 349*, 13.12.1990, p. 21-25.

[122] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom, *OJ L 180*, 9.7.1997, p. 22-27.

[123] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high activity sealed radioactive sources and orphan sources, *OJ L 346*, 31.12.2003, p. 57-64.

[124] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, *OJ L 159*, 29.6.1996, p. 1-114.

[125] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, *OJ L 13*, 17.1.2014, p. 1–73.

[126] Council Resolution of 22 July 1975 on the technological problems of nuclear safety, *OJ C 185*, 14.8.1975, p. 1-2.

1. The judgement of the ECJ of 10 December 2002 (Case C-29/99).

The starting point of the EU field in nuclear energy was that the safety of the installations and the management of the waste used in them is a limited competence of the Member States, as it has been considered by the European Commission in several reports[127].

As we can extract from what has been explained, there has not been a uniformity in legally binding regulations on nuclear safety or safety in waste management. The inflection point occurred when the European Commission started a procedure for the EURATOM Community to join the CNS[128]. This started a discussion about the communitarian competence on nuclear safety, raising the case to the Court of Justice of the European Union (ECJ).

The judgement of 10th December of 2002 has had an essential relevance in the institutional debates of the directives that we will see *infra*[129].

The case of the *Commission against the Council* started a debate to analyse the competences of the EURATOM Community to adhere to the CNS. For the correct addition of the Community to the Convention, it was necessary that the own treaty admitted the possibility of adhesion of international organizations (permitted by article 30.4 of the CNS), that the addition was adjusted to the conditions imposed by the own EURATOM Treaty (article 101.1 and 2) and that the Community had competences in some areas of the CNS.

The Decision adopted by the Council on 7th December of 1998[130] considered that articles 15 and 16.2 of the CNS were appliable to the EURATOM Community (the ones referring radiological protection of people) and the parts of articles 1 to 5, 7.1,

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[127] In the Communication from the Commission to the Council and the European Parliament [COM (2002) 605 final, 6.11.2002, p.11], it is recognised that "[…] the fact that Member States maintain exclusive competence with regard to the technological aspects of safety […]", (p.13) "[…]calls for regular reports from Member States'[…]", (p.15) "[…] Member States will be obliged to transmit reports on the measures taken to meet their obligations and on the state of safety of installations under their supervision […]".

[128] TRÜE, C., "Legislative competences of Euratom and the European Community in the energy sector: the nuclear package of the Commission", *European Law Review,* 28, 2003, p. 664-685.

[129] MORALES, A., *La regulación nuclear globalizada,* La Ley, 2009, p. 21.

[130] COUNCIL OF THE EUROPEAN UNION, 2148th Council Meeting General Affairs, C98/431, 6-7 December 1998.

14.ii); and 20 to 35 that directly affect the scope of article 15 and 16. According to this, the Decision 1999/819/Euratom of 16th November of 1999[131] approved the adhesion of the EURATOM Community to the CNS. Therefore, all matters related to nuclear safety and nuclear facilities were excluded from the Community's sphere of competence as long as they do not carry with them obligations on radiological protection, a matter expressly included in article 2 and in Chapter 3 of Title II of the EURATOM Treaty.

Leaving aside both decisions, we will focus on the judgment of 10th December of 2002[132], which decides that the declaration of competences of the Community to adhere to the CNS must include articles 7, 14, 16.1 and 3, and 17 to 19, annulling the declaration made by the Council.

It is commonly accepted by all that the areas contained in articles 15 and 16.2 of the CNS on the exposure of people to ionizing radiation, as well as the information to the possibly affected population on plans for nuclear emergencies, are shared competences between the Community and Member States[133]. Therefore, the question made to the Court is whether there are other competences besides the ones mentioned before.

There is no explicit provision in the EURATOM Treaty on nuclear safety; however, article 2.b) and Chapter 3 of Title II of the Treaty recognize the need to create uniform safety standards for radiation protection, being possible only through the control of the harmful sources. Paragraph 82 of the judgement says that

> "it is not appropriate, in order to define the Community's competences, to draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation".

[131] Commission Decision of 16 November 1999 concerning the accession to the 1994 Convention on Nuclear Safety by the European Atomic Energy Community (Euratom), *OJ L 318*, 11.12.1999, p. 20-20.
[132] ECJ, *Commission of the European Communities v. Council of the European Union*, C-29/99, Judgement of 10 December 2002, EU:C:2002:734.
[133] MORALES, A., *op cit.*, p. 22.

Through the judgment, the powers of the EURATOM Community in nuclear safety are assumed, always linked to radiation protection. This link was clarified by the Advocate General (Mr. *F. G. Jacobs*) in his conclusion of the Case 29-99 delivered on 13th December 2001, explaining the historical evolution of the disciplines of nuclear safety and radiation protection and concluding that any nuclear safety measure must include the analyses precise on the dose limit to be received by people and on the ALARA[134] principle. He also pointed out that this close link was a sign of the international trend (from the IAEA and the ICRP work) to consider that nuclear safety combines technical safety (protection of radioactive sources) with radiation protection (dose control)[135].

To sum up, the EURATOM Community became competent in[136]:

i. Legislate or demand legislation (article 7).
ii. Control and verify the security (article 14).
iii. Participate in all issues related to nuclear emergencies that are in the CNS scope (article 16).
iv. Be informed and participate in the choice of nuclear sites, design, construction and operation, always from the point of view of radiation protection, which, from this judgement, cannot be separated from nuclear safety (articles 17, 18 and 19).

The ECJ interpreted the text of the treaty extensively, allowing the creation of binding nuclear safety norms (never seen to date), while the Council acted conservative and intended to preserve national jurisdiction in all matters related to nuclear facilities.

Based on the recognized competences and the positions adopted, the Commission presented the 30th January of 2003 the proposals for two nuclear directives, one related to nuclear safety and the other to the management of radioactive waste. We will study both initial proposals first, analysing later the latest versions of those directives jointly with the Directive that establish basic safety standards for the

[134] Acronym to "As low as Reasonably Achievable".
[135] ECJ, *Commission of the European Communities v. Council of the European Union*, *op. cit.*, opinion of the Advocate General Jacobs delivered on 13 December 2001, EU:C:2001:680.
[136] MORALES, A., *op cit.*, p. 23.

protection against the dangers arising from the exposure to ionizing radiation mentioned before.

2. The Nuclear proposals.

The Commission presented, in the same final file, the Proposal for a Council Directive (Euratom) defining the basic obligations and general principles in the field of safety of nuclear installations [137] (Nuclear Safety Directive), and the Proposal for a Council Directive (Euratom) on the management of spent fuel and radioactive waste[138] (Waste Directive).

Both directives were legally based on article 31 of the EURATOM Treaty, establishing a harmonized legal development on nuclear safety within the Union and aimed to guarantee the maintenance of a high level of nuclear safety in the EU.

a. Nuclear Safety Directive proposal.

The objective of the Directive is to establish the basic obligations and general principles recognized in article 30 of the EURATOM Treaty "to ensure the protection of the general public and of workers against the dangers of ionising radiation from nuclear installations" (article 1). Regarding the general scope, the Directive "applies to all nuclear installations, including after the end of their operation", away from the CNS prescription that only affects nuclear power plants. Therefore, both research reactors, mines and other nuclear cycle facilities fall within the scope of the Directive[139].

Articles 3 and 4 are dedicated to the regulatory body, establishing its independence "from any other body or organisation whether private or public, concerned with the promotion or utilisation of nuclear energy" (article 3) and its functions, which range

[137] Draft proposal for a Council (Euratom) Framework Directive setting out basic obligations and general principles on the safety of nuclear installations, COM (2003) 32 final, 30.01.2003.
[138] Draft proposal for a Council (Euratom) Directive on the management of spent nuclear fuel and radioactive waste, COM (2003) 32 final, 30.01.2003.
[139] MORALES, A., *op cit.*, p. 29.

from the regulation of the safety of the nuclear installation to the granting of licenses and control of the design or operation of the installation (article 4).

Regarding the safety of nuclear installations, article 5 contains four instruments to achieve a high level of safety. Indeed, Member States are requested to "establish and maintain effective arrangements in nuclear installations against potential radiological hazards in order to protect individuals, society and the environment from harmful effects of ionising radiation from such installations" (5.a) and to "implement all further measures to guarantee safety in nuclear installations" (5.c), amongst others.

Article 6 includes the principle of safety priority for any practice related to the operation of nuclear facilities (based on operational protection measures), while article 7 includes the list of obligations to which the incumbent companies are subject. These include the operation of nuclear facilities "with the common safety standards applicable to them" and the measures imposed by the regulatory body.

Article 8 establishes the inspection regime, according to which the regulatory body will carry out inspections at nuclear facilities (including during decommission) and in which the authorization holder will have the obligation to submit to them.

Article 9 requires the prevision of financial resources to guarantee the safety of facilities and dismantling. For its part, article 10 is dedicated to the so-called "safety experts". These experts are intended to be "available for all nuclear safety-related activities" and "that opportunities for continuous theoretical and practical training exist for the staff concerned".

Regarding operating incidents, article 11 of the proposal considers that there should be programs to prevent accidents and reduce them where appropriate. Therefore, the holders will be obliged to report the incidents and the measures adopted to the regulatory body.

On monitoring the application of this new regulatory system related to nuclear safety, article 12 establishes that "the Commission shall carry out verifications of safety authorities", in order to ensure the maintenance of a high level of nuclear safety in the Member States.

Article 13 entitled "Reports" establishes that "Member States shall submit a report to the Commission every year […] on the measures taken to fulfil their obligations under this Directive".

Finally, it should be mentioned that there is an annex on decommissioning funds, describing how these funds should be economically endowed, determining the terms and expenses to be covered until the long-term safe management of spent fuel and radioactive waste produced.

b. Waste Directive proposal.

The principles that govern the management of all hazardous wastes must guarantee a high level of public and worker safety, as well as environmental protection. For spent nuclear fuel and radioactive waste, the application of these principles must ensure that people, society, and the environment are protected against the harmful effects of ionizing radiation. In those years, these principles guided the community action, consisting basically on research works and political legislative initiatives, such as the approach taken in the Community Action Plan [140] to ensure an equivalent and acceptable level of safety in the EU and the 1999 report on the radioactive waste management situation in the EU[141].

Furthermore, the Commission's Green Paper on the security of energy supply in the EU[142] pointed out the need to find acceptable solutions to the management of radioactive waste, considered one of the main concerns in the nuclear field.

In this sense, we will analyse the proposal regarding the management of spent fuel and radioactive waste.

The object and scope, regulated in article 1, extends to the safe management of radioactive waste and spent nuclear fuel to "ensure […] that workers, the general

[140] Council Resolution of 15 June 1992 on the renewal of the Community Plan of Action in the field of radioactive waste, *OJ C 158*, 25.6.1992, p. 3-5.

[141] Communications from the Commission to the Council "Communication and fourth report on present situation and prospects for radioactive waste management in the European Union", COM (98)799, 11.01.1999.

[142] COMMISSION, Towards a European strategy for the security of energy supply, Green paper, COM/2000/0769, 29.11.2000.

public and the environment are adequately protected from harmful effects of ionising radiation, both now and in the future", "achieve and maintain a high level of safety […] to protect human health and the environment" and "to enhance effective public information and, where appropriate, participation" to ensure the required transparency in the relevant decision-making processes.

From this first article we can made two observations: on one hand, the protection of the effects of radiation is sought (as habitual in the developments of Chapter 3 of Title II of the EURATOM Treaty), although it wants to protect the environment without considering that is not protected in the text of the 1957 Treaty; and on the other hand, the second purpose announced is the consideration of the public opinion, understanding that a negative opinion could condition the decision-making process.

The general requirements for the management of spent fuel and radioactive waste are set out in article 3, which require Member States to take all necessary measures to ensure that spent fuel and radioactive waste "are managed in such a way that individuals, society and the environment are adequately protected against radiological hazards" and imposing that the production of radioactive waste "is kept to the minimum practicable", developing the legal and regulatory framework necessary to achieve the purposes of the Directive, proposing to fulfil this with the creation of a regulatory body. Adequate financial resources will also be available for the safe management of radioactive wastes and spent fuel produced, respecting the "polluter pays principle". Lastly, Member States shall ensure the "effective public information and […] participation" in order to achieve a high level of transparency in issues related to spent fuel and radioactive wastes.

This list of requirements includes the four fundamental axes of waste policy: production, security in state-controlled management (requirement of a legal and regulatory framework including the existence of a regulatory authority), the need to have an adequate financial guaranteed, and lastly, the avoid of the traditional opacity of decisions in this matters regarding the population[143].

[143] MORALES, A., *op cit.*, p. 37.

Article 4 is entitled "Programme for the management of radioactive waste". As it is said, each Member State will establish a "clearly defined programme for radioactive waste management", covering all stages of management (including spent fuel that is not subject to reprocessing contracts or, in the case of research reactor fuel, take-back agreements). Long-term management should be contained in the programs, including a schedule for the final storage.

This article has been the most criticized of the Directive. Firstly, the proposed deadlines are impossible to achieve, secondly, the solution of deep geological storage prevails over other possibilities that were under investigation, and finally, a single rigid calendar is offered for 25 States with very different situations in everything related to waste management[144].

Article 5 is dedicated to technological development and research in radioactive waste management. The Commission "shall identify common areas of research and technological development that could be co-ordinated at the Community level", and "shall encourage co-operation between the Member States". For its part, article 6 establishes investments, where the Commission "shall take into consideration the progress made by Member States towards meeting the targets set out in Article 4 for authorisation of a disposal facility or disposal facilities for the different forms of radioactive waste".

As it is established in article 7, and as in the Nuclear Safety Directive, Member States must submit a report to the Commission every three years on the measures taken and the situation of spent fuel and waste in the country.

Lastly, the single annex of the Waste Directive provides various considerations on the final storage of radioactive waste. Indeed, a phased approach to development, technical demonstration, and the creation of a definitive radioactive waste storage system is considered "*necessary and unavoidable*"[145].

[144] *Ibid*, p.38
[145] The italic is ours.

After having seen both proposals, we can conclude that there is no logical parallelism for a set of joint measures. In the last case, an inspection regime is not foreseen, and waste management principles and obligations are not determined. The definitions for the same concept do not coincide, and the general safety standards for waste that (required in nuclear facilities) are not imposed.

All this led to the fact that the study of both proposals needed to be separated, given the possibility of saving one so the European Parliament could approve it, and to the detriment of the other (it was estimated that the nuclear safety Directive was going to fall due its lack of definition and added value)[146].

C. EU/Euratom regulation relating to nuclear safety and radiation protection.

1. Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations, and Directive 2014/87/Euratom amending Directive 2009/71/Euratom.

As it is expressed in article 1, the objectives of the Directive[147] are to "establish a Community framework in order to maintain and promote the continuous improvement of nuclear safety", and to "ensure that Member States shall provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionizing radiations from nuclear installations. Although the environment is not directly protected, recital (5) recognises the need to "*protect the population and the environment against risks of nuclear contamination"*[148].

[146] *Ibid*, p. 39.
[147] Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, *OJ L 172*, 2.7.2009. p. 18-22.
[148] The italic is ours.

The provisions in the Directive apply to "any civilian nuclear installation [149] operating under a licence as defined in Article 3(4)[150] at all stages covered by this licence" (article 2.1). In line with article 193 TFUE, paragraph 2 of article 2 sets out the right of Member States to take "more stringent safety measures" in everything covered by the Directive.

Article 3 defines the concept of nuclear safety, meaning

> "the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionizing radiations from nuclear installations" (article 3.2).

Once the objectives and the scope of application are defined, Chapter 2 of the Directive is dedicated to the obligations. Articles 4 and 5 set up the need to "establish and maintain a national legislative, regulatory and organisational framework […] for nuclear safety of nuclear installations", with responsibilities as the adoption of national nuclear safety requirements (article 4.1.a) and the provision of a system of licensing, with the prohibition of operation of nuclear installations without that license (article 4.1.b). It also remarks the need to establish and maintain a "competent regulatory authority in the field of nuclear safety of nuclear installations" (article 5.1), with legal powers as the ability to require the licence holder to comply with national nuclear safety requirements (article 5.3.a), amongst others.

As we can extract from the first five articles, the license is the base of everything related to nuclear safety and the safety of nuclear installations. For this reason, article 6 establishes that Member States shall ensure that "the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder", remarking

[149] The concept of nuclear installation is defined in article 3.1, meaning "(a) an enrichment plant, nuclear fuel fabrication plant, nuclear power plant, reprocessing plant, research reactor facility, spent fuel storage facility; and (b) storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations listed under point (a)".
[150] In line with that, 'licence' is defined as "any legal document granted under the jurisdiction of a Member State to confer responsibility for the siting, design, construction, commissioning and operation or decommissioning of a nuclear installation".

that the responsibility "cannot be delegated" (article 6.1). The national framework set up in article 4 requires the licence holder to verify and asses the safety of nuclear installations (article 6.2), highlighting for our study that the assessment includes the verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be "significantly affected by ionizing radiation" (article 6.3).

Member States, under article 9, shall submit a report to the Commission on the implementation of this Directive by 22 July 2014, and every three years thereafter[151]. They shall also arrange, at least every 10 years, for periodic self-assessment of their national framework and competent regulatory authorities (article 9.3).

Directive 2014/87/Euratom[152] amended Directive 2009/71/Euratom to introduce further provisions on nuclear safety and radiation protection after the *Fukushima* accident in Japan in 2011. This accident renewed attention worldwide on the measures needed to minimise risks and ensure the most robust levels of nuclear safety (recital 5), proving the need to strength the provisions of Directive 2009/71/Euratom (recital 6). The *Fukushima* accident showed also that the consequences of nuclear accidents can go "beyond national borders" (recital 10), and highlighted again, after Three Mile Island and Chernobyl accidents, the critical importance of the containment function, which is "the last barrier to protect people and the environment against radioactive releases resulting from an accident" (recital 20).

Due to that, Directive 2009/71 should be amended[153] to include a high-level EU nuclear safety objective covering all stages of the lifecycle of nuclear installations (applying to the siting, design, construction, commissioning, operation, and decommissioning). In particular, this objective "calls for significant safety enhancements in the design of new reactors for which the state of the art knowledge

[151] Taking advantage of the review and reporting cycles under the Convention on Nuclear Safety.
[152] Council Directive 2014/87/Euratom of 9 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations, *OJ L 219*, 25.7.2014, p- 42-52.
[153] In view of the technical progress achieved through the provisions of the IAEA and by the Western European Nuclear Regulators Association (WENRA).

and technology should be used, taking into account the latest international safety requirements" (recital 15).

For that reason, article 3 regarding definitions introduced the concepts of 'accident'[154] and 'incident'[155] amongst others, and articles 4 and 5 change the general obligations to cover "all stages of the lifecycle of nuclear installations" (article 4.1.b) and to address properly upcoming accidents.

In order to ensure a stringent security in the national framework, article 6 (a) regarding licenses includes the "responsibility for the activities of contractor and sub-contractor whose activities might affect the nuclear safety of a nuclear installation", and includes also in the license holder responsibilities the obligation to address accidents (article 6.e.ii).

Regarding specific obligations, "Section 2" is inserted after the original article 8. The objective of it is to prevent accidents and, if and accident occurs, mitigate its consequences and avoiding:

(a) Early radioactive releases that would require off-site emergency measures but with insufficient time to implement them.
(b) Large radioactive releases that would require protective measures that could not be limited in area or time.

Finally, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 August 2017[156].

[154] Meaning "any unintended event, the consequences or potential consequences of which are significant from the point of view of radiation protection on nuclear safety".
[155] Meaning "any unintended event, the consequences or potential consequences of which are not negligible from the point of view of radiation protection on nuclear safety".
[156] This Directive has been transposed into Spanish State law in the "*Real Decreto 1440/2018, de 23 de noviembre, por el que se aprueba el Reglamento sobre seguridad nuclear en instalaciones nucleares*".

2. *Directive 2011/70/Euratom establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.*

The Waste Directive's[157] structure is based on the Nuclear Safety Directive and the Joint Convention, by which it is inspired. As it is said in recital 21, radioactive waste and spent fuel considered as waste requires containment and isolation from humans and the living environment to "protect human health and the environment against the dangers arising from ionising radiation". The objective of the Waste Directive is to establish a Community framework for ensuring responsible and safe management of spent fuel and radioactive waste to "avoid imposing undue burdens on future generations" (article 1.1). The concern of future generations was, as we have seen, established in principle 3 of the *Rio Declaration*.

The Directive has a wide scope. As defined in article 2, it applies to all stages of spent fuel and radioactive waste as long as the materials result from civilian activities. The Waste Directive excludes:

i. Waste arising from uranium mining and milling activities. These wastes are already regulated by the Directive on the management of waste from extractive industries[158].
ii. Radioactive waste resulting from defence activities. As the ECJ has established in its jurisprudence, the EURATOM Community is not competent to regulate the use of nuclear energy for military purposes[159].
iii. Authorised releases as they are covered already by legislation under the EURATOM Treaty, in particular the Basic safety standards Directive that we will study later.

[157] Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, *OJ L 199,* 2.8.2011, p. 48-56.
[158] Directive 2006/21/CE of the European Parliament and of the Council of March 2006 on the management of waste from extractive industries, *OJ L 102*, 11.4.2006, p. 15-34.
[159] ECJ, *Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland,* C-61/03, Judgement of the Court (Grand Chamber) of 12 April 2005, ECLI:EU:C:2005:210, and C-65/04, Judgement of the Court (First Chamber) of 9 March 2006, ECLI:EU:C:2006:161.

Article 3 defines the concept, amongst others, of 'radioactive waste'[160] and 'spent fuel'[161] and what its 'management'[162] consists.

Article 4 sets out the general principles for the management of spent fuel and radioactive waste, inspired by those promoted in the IAEA context and introducing some important restrictions on the export of radioactive waste. The general principles are the following:

i. Each Member State shall establish and maintain national policies on spent fuel and radioactive waste and "have ultimate responsibility for management of the spent fuel and radioactive waste generated in it" (article 4.1)
ii. When the waste is shipped for processing or reprocessing to a Member State or a third country, the ultimate responsibility for the safe and responsible disposal of those materials "shall remain with the Member State or third country from which the radioactive material was shipped" (article 4.2).
iii. The generation of radioactive waste "shall be kept to the minimum which is reasonably practicable" (article 4.3.a).
iv. Due consideration shall be given to the "interdependencies between all steps in spent fuel and radioactive waste generation and management" (article 4.3.b).
v. Spent fuel and radioactive waste shall be "safely managed" in the long term with the means of passive safety features (article 4.3.c and recital 23).
vi. The implementation of measures shall follow a "graded approach" (article 4.3.d), which means that the stringency of measures should be commensurate with the level of risks of the particular activity or facility[163].

[160] Meaning "radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Member State or by a legal or natural person whose decision is accepted by the Member State, and which is regulated as radioactive waste by a competent regulatory authority under the legislative and regulatory framework of the Member State".
[161] Meaning "nuclear fuel that has been irradiated in and permanently removed from a reactor core; spent fuel may either be considered as a usable resource that can be reprocessed or be destined for disposal if regarded as radioactive waste".
[162] Meaning "all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal, excluding off-site transportation.
[163] BLOHM-HIEBER, U., "The Radioactive Waste Directive", *Nuclear Law Bulletin*, 2012, p. 25.

vii. Those who generate spent fuel and radioactive waste shall bear the cost of its management (article 4.3.e).

viii. Lastly, "an evidence-based and documented decision-making process" shall be applied with regard to all stages of the management of spent fuel and radioactive waste (article 4.3.f).

Article 4.4 establishes also the export control system, with the general principle that "radioactive waste shall be disposed of in its Member State in which it was generated", but with the exceptions that:

i. The country of destination has concluded an agreement with the EURATOM Community covering spent fuel and radioactive waste management or is a party of the Joint Convention.

ii. The country of destination has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by this Directive; and

iii. The disposal facility in the country of destination is authorised for the radioactive waste to be shipped and is managed in accordance with the requirements set down in the radioactive waste management and disposal programme of the country of destination.

Regarding the obligations of establishing a national framework, a competent regulatory authority and the license holders' powers (articles 5 to 7), we must point out that they are in line with the ones in the Nuclear Safety Directive, revealing together a coherent framework for the responsible and safe use of nuclear energy in the EU, something that, as we have seen *supra,* was missing in the directives proposals of 2003.

Policies and programmes for the management of spent fuel and radioactive waste lack the necessary foundation when financing is not ensured[164]. For this reason, article 9 requires Member States to ensure that the national framework "require that adequate financial resources be available when needed", taken due account of the responsibility of spent fuel and radioactive waste generators.

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[164] *Ibid*, p. 31.

Unlike the Nuclear Safety Directive, and to control the transposition of the Directive into national law, article 11 requires each Member State to ensure the implementation of its national programme for the management of spent fuel and radioactive waste, called "national programme". Member States shall notify the Commission of their national programme for the first time in August 2015, and thereafter every three years.

Finally, under article 15, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 August 2013[165].

3. *Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/64/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.*

The Directive 2013/59/Euratom created a common framework of everything related to the protection against the dangers from the exposure to ionizing radiation, repealing and unifying a wide range of directives regarding public, operational and medical exposure to radiation and on the control of high activity sealed radioactive sources.

To start, recital 27 of the directive refers directly to the environment. It states that "*the contamination of the environment may pose a threat to human health"*[166], and that the EU's legislation has regarded such contamination only as a pathway of exposure to members of the public directly affected by radioactivity. In fact, it establishes that "the state of the environment can impact long-term human health",

[165] This Directive has been transposed into Spanish State law in the "*Real Decreto 102/2014, de 21 de febrero, para la gestión responsable y segura del combustible nuclear gastado y los residuos radioactivos".*

[166] The italic is ours.

calling for a policy protecting the environment against the harmful effects of ionizing radiation and taking into account the recognised scientific data[167].

The Basic Safety Standards Directive establishes uniform basic safety standards for the "protection of the health of individuals subject to occupational, medical and public exposure" against the dangers arising from ionizing radiation. Although article 1 differentiates three types of exposure, we will only focus on the public one. Furthermore, article 2 establishes that the directive applies to "any planned, existing or emergency exposure situation" which involves a risk from exposure to ionizing radiation which "cannot be disregarded from a radiation protection point of view or with regard the environment in view of long-term human health protection. Unlike the Nuclear Safety and the Waste Directives, the Basic Safety Standards Directive refers directly to the environment, although the protection is for long-term human health and not for the environment itself.

Chapter III entitled "system of radiation protection" establishes the general principles of radiation protection and the system of dose of radiation exposure limitation[168] to safely protect workers (article 9), pregnant and breastfeeding workers (article 10), apprentices and students (article 11) and the general public (article 12). Specifically, article 5 points out that Member States shall establish a regime of regulatory control which reflect a "system of radiation protection based on the principles of justification, optimisation and dose limitation", defined as:

(a) Justification: Decisions shall be justified in the sense that such decisions shall be taken "with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause".
(b) Optimisation: Radiation protection of individuals subject to public exposure shall be optimised with the aim of "keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals

[167] Such as published by the EC, ICRP, United Nations Scientific Committee on the Effects of Atomic Radiation and the IAEA.
[168] Dose limitation understood as the value of the effective doses (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual.

exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors".

(c) Dose limitation: In planned exposure situations, the sum of doses to an individual "shall not exceed the dose limits laid down for occupational exposure of public exposure".

Chapter VI and VII are dedicated to occupational and medical exposure respectively, while Chapter VIII is dedicated to public exposure. Section 1 entitled "Protection of members of the public and long-term health protection in normal circumstances" establishes the controls needed to secure the safety of the relevant facilities (article 65) and emphasizing an assessment to demonstrate that "environmental criteria for long-term human health protection are met", the estimation of doses to the member of the public (article 66), the monitoring of radioactive discharges (article 67) and the tasks for the undertaking (article 68), pointing out the importance of "measuring and assessing exposure of members of the public and radioactive contamination of the environment".

For the emergency exposure, Section 2 establishes the need for an emergency response (article 69), having Member States to ensure that the provision is made for protective measures with regard to the radiation source, the environment and individuals. Section 3 for existing exposure situations establishes the need of an environmental monitoring programme (article 72) and the optimised protection strategies for managing contaminated areas (article 73), understanding 'contamination' as the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body (article 2.18).

Lastly, and under article 106, Member States shall transpose the directive by 6 February 2018[169].

[169] This Directive has been partially transposed into Spanish State law in the "*Orden de ETU/1185/2017, de 12 de noviembre, por la que se regula la desclasificación de los materiales residuales generados en instalaciones nucleares*".

V. CONCLUSIONS.

FIRST. The damages generated by nuclear energy are beyond our reach and control. Therefore, it is important to understand that any safety and radiation protection measure will never be enough, given the extent of the nuclear energy damage.

SECOND. The control and maintenance of nuclear installations is one of the keys to ensure nuclear safety, as well as the possible damage caused by their radiation. But it is important to stand out and highlight how the three largest nuclear accidents occurred throughout history have taught us that the "safety" of nuclear facilities is relative, since it is necessary to take into account all possible risk situations where a nuclear power plant can be involved.

THIRD. The system of protection of human health has been much easier and simpler to make than the environmental one, due to the greater access to information on how radiation affects the human body. As regards the environment, the great diversity of factors that come into play, as well as the lack of relevant data on the effects of radiation on biota, has made the task of creating an overall framework of protection much more complicated. In this point, we must highlight the creation of the 'Reference Individuals', and the subsequent adaptation to the environment with the 'Reference Animals and Plants'. As the ICRP has said, the lack of relevant data and the nature of the dynamics of wild populations and plants makes difficult the creation of an overall framework of protection of the environment. Therefore, it will be necessary to wait for future studies and investigations to approach a more precise protection of the environment.

FOURTH. Although there are difficulties to achieve a real protection of human health and the environment, as well as to provide a guaranteed level of safety in nuclear installations, several actions have been taken at the universal level to pursue these objectives. Thus, since the end of the 20th century, we can find specific binding regulations relating to nuclear safety and the safe management of the spent fuel and radioactive waste. Before these regulations, soft law was the main kind of regulation in this field, so the adoption of these conventions was a huge step in the fight for nuclear safety and protection from ionizing radiation. Even so, soft law regulation continues today to have a great relevance in the area. It is worth noting that soft law was and continues to have an importance role in the regulation of the nuclear energy field, considering how dangerous it is and the severity of its damages.

FIFTH. From the universal regulation that has to do with nuclear safety and radiation protection, we shall highlight that from the beginning of the uses of nuclear energy the international community was aware of the damages caused by that energy to both humans and the environment (although its true scope was not known), but it took many years to create binding regulations that legally ensure everything stated above relating nuclear safety, radioactive waste management and direct radiation protection.

SIXTH. Analysing the legal background, we find some differences between the regulation at the universal and the European level. In one hand, at the universal level, due to the weak common denominator between the States, the adaptation of regulations to cope with the problem is more difficult. In the other hand, the common culture of the EU, the reduced number of Member States in comparison with the universal level, and the share interest of its Members for the environmental protection, makes easier the adoption of efficient regulation, making stronger instruments than at the universal level.

SEVENTH. From the EU/EURATOM regulation, and following the steps of the international community, the need to establish a common framework in everything related to nuclear safety was seen, since up to the moment it was competence of each Member State. The entry of the EURATOM community into the CNS was chosen first, as well as the subsequent incorporation of the content of both conventions into Directives. The reason for the Directives was to have a common framework of nuclear safety and management of radioactive waste, and as we have seen, the proposals for European Directive did not offered that solution.

EIGHT. The judgement of the ECJ of 10th December 2002 was crucial for the creation of the proposals for the nuclear safety and radioactive waste Directives, as well as the establishment of the common European framework of both topics.

Through the judgement, and highlighting the conclusion of the Advocate General Mr. F. G. Jacobs, the EURATOM community assumed powers in nuclear safety, but only in the aspects related to radiation protection. It was also clear that the safety of nuclear installations and the consequent protection of the population were something strictly linked.

NINTH. From the EU/EURATOM we must emphasize that in their latest updated versions they do establish this common approach to the nuclear situation, as well as the incorporation of all scientific studies from different organizations such as ICRP, IAEA and WENRA. It is important to highlight the Directive establishing basic safety standards for the protection against the dangers from the exposure to ionizing radiation, without being a direct result of the universal conventions seen at the work, establishes basic principles and obligations regarding the protection of human health and the environment from radiation exposures, creating furthermore a common framework in everything related to this subject in previous Directives.

TENTH. Although great strides are being made in ensuring the protection of human beings and the environment, we do not know when we will come to understand the reality of the effects of ionizing radiation in every single living being on the planet. What is clear is that scientific advances, with their subsequent incorporation into the legal word, will be the key to achieve this.

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