

# Chapter 7

## Legal Imputation of Radiation Harm to Radiation Exposure Situations



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**Abstract** The doctrine for legal imputation (including the derivative concepts of legal charging, suing, indicting, prosecuting and judging) of detrimental health effects to those responsible for radiation exposure situations has been a matter of debate for many years and its resolution is still unclear. While the attribution of harm in the situations involving high radiation dose is basically straightforward, the challenge arises at medium doses and becomes a real conundrum for the very common situations of exposure to low radiation doses. The ambiguous situation could be construed to be a Damocles sword for the renaissance of endeavours involving occupational and public radiation exposure. This chapter describes the epistemological situation on the attribution of radiation health effects and the inference of radiation risks, relying on estimates from the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported to the UN General Assembly. It discusses the implications of UNSCEAR's refined paradigm for assigning legal liability. The chapter concludes with a recommendation to develop an international legal doctrine on the ability to impute detrimental radiation health effects.

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## 7.1 Aim

The purpose of this chapter is to address the *legal imputation*<sup>1</sup> of *radiation harm*<sup>2</sup> to *radiation exposure situations*.<sup>3</sup> The concept of legal imputation is used as a precursor of its derivative legal concepts of suing and prosecuting, charging, indicting and judging.

The legal imputation of radiation harm has been controversial, particularly for situations involving low radiation doses. The lack of clarity on such an important issue is a challenge for the normal development of human endeavours involving radiation exposure of people, such as the generation of nuclear electricity and the use of radiation and radioactivity in medicine, industry and research.

Therefore, this chapter aims to promote an international common understanding on the issue.

The chapter contains the following:

- A summary description of the basic scientific international consensus on radiation health effects, which is aimed at providing a background on the issue. This is followed by a discussion on estimating effects and imputing harm and a portrayal of the fundamental paradigm, including a discussion on verifiable facts vis-à-vis subjective conjectures.

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<sup>1</sup> The concept of *legal imputation* is used to mean actions based on law for attributing radiation harm to radiation exposure situations. It is used as a precursor of its derivative concepts of legal charging, suing, indicting, prosecuting and judging. In a legal context, imputing means ascribing to someone causing physical injury, actual or potential ill effects that are attributable to radiation exposure, namely ascribing responsibility for effects of radiation exposure. It is to be noted that attributing is different than imputing, but unfortunately the terms have been used internationally as synonyms. See ILO et al. 2010.

<sup>2</sup> The concept of *radiation harm* is used to mean any *radiation health effect* or physical injury incurred by people, namely identified individuals or populations as a whole, which can be attested as having been inflicted by radiation exposure, where *radiation* is used to mean ionizing radiation and *radiation health effect* is used to mean any health effect generated by exposure to radiation.

<sup>3</sup> The concept of *radiation exposure situations* is used to mean any set of circumstances in which people are subjected to states or conditions of being irradiated by ionizing radiation, either from a source outside the body or a source incorporated within the body, where a source is anything that may cause radiation exposure, such as by emitting ionizing radiation or by releasing radioactive substances or radioactive material.

- A discussion on the *attribution*<sup>4</sup> of radiation harm vis-à-vis the *inference*<sup>5</sup> of *radiation risk*<sup>6</sup> from radiation exposure situations.
- The related issue of *attestation*,<sup>7</sup> by the so-called *expert witness*,<sup>8</sup> of the factual occurrence of radiation health effects.
- The consequent possibilities of *legal imputation* of such radiation harm to those radiation exposure situations.

## 7.2 Summary of the Basic Scientific Consensus

A universal consensus on the estimates of radiation health effects has been agreed internationally over the years by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and routinely reported to the United

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<sup>4</sup> *Attribution* is used to mean the ascribing of a health effect to radiation exposure using objective factual evidence.

<sup>5</sup> *Inference* (in contrast with attribution) is used to mean the process of drawing conclusions from subjective conjectures involving indirect scientific observations, evidence and reasoning in the presence of uncertainty (while the use of inference is usually focused on prospectively inferring risk, note that estimating an *assigned share* or *probability of causation* is also an inference, but retrospective).

<sup>6</sup> *Radiation risk* is used to mean the probability that a health effect associated to radiation exposure (e.g. onset of cancer) may occur (i.e. it is a prospective notion) during a given time period (e.g. the rest of life following an exposure). Radiation risks should only be attributed by using factual evidence from epidemiological investigations of disease rates in previously exposed populations (i.e. based on past observations); nonetheless, it is to be noted that the results from such retrospective analyses have been also used to make inferences about the risk for other exposure situations involving different populations for which direct epidemiological data were not available.

<sup>7</sup> *Attestation* is used to mean that an *expert witness* provides or serves clear evidence by formally declaring that a radiation effects exists or is the case.

<sup>8</sup> *Expert witness* is used to mean a specialist of radiation effects who may present his/her expert opinion without having been a witness to any occurrence relating to a radiation-related lawsuit or criminal case, but just to the factual occurrence of the effects, as follows:

*Radiopathologists* are expert witnesses of the factual occurrence of radiation health effects that can be diagnosed in individuals, namely they are recognized and certified scientists who study the causes and effects of radiation induced diseases, especially by examining laboratory samples of body tissue for diagnostic or forensic purposes.

*Radioepidemiologists* are expert witnesses of the factual occurrence of radiation health effects that are not individually diagnosable but can be only estimated in populations (i.e. they are recognized and certified scientists with expertise in medical statistics, the branch of medicine that deals with the incidence and distribution of diseases associated with radiation exposure).

*Radiobiologists* are expert witnesses of the factual occurrence of biological changes attributable to radiation exposure, by analysing specialized bioassay specimens, such as some haematological and cytogenetic samples (i.e. they are recognized and certified scientists with expertise in the branch of biology concerned with the effects of ionizing radiation on organisms, organs, tissues and cells).

*Radioprotectionists* (also known as radiation protection experts or health physicists) are expert witnesses associated with conjecturing and inferring radiation risks (i.e. they are certified scientists who are duly recognized as having expertise on the protection of people from harmful effects of exposure to ionizing radiation, and on the means for achieving such protection).

Nations General Assembly (UNGA). UNSCEAR is the international intergovernmental organization assigned by UNGA to estimate the global levels and effects of radiation.

The fundamental theses under the international paradigm, over which the chapter will be founded, are presented simplistically as follows:

- There is scientific consensus that exposure to high levels of radiation doses incurred over a relatively short time results in acute (i.e. critical, serious) harmful effects on the exposed individuals. These effects can be diagnosed, proven and *attested* by qualified *radiopathologists*. In sum, an observed health effect in an individual could be unequivocally attributed to radiation exposure if the individual were to experience tissue reactions (often referred to as ‘deterministic’ effects), and differential pathological diagnosis were achievable that eliminated possible alternative causes. Such deterministic effects are experienced as a result of high absorbed doses, incurred in a relatively short period of time, as might arise following exposure due to accidents or radiotherapy. Such deterministic effects can therefore be individually imputed to the situation through a classic *lawsuit*.<sup>9</sup>
- At lower doses, a collective harm can be incurred by the populations being exposed, which may be expressed as increases in the incidence of certain effects. Such increases can be assessed, proven and *attested* by qualified *radioepidemiologists*. These health effects in an individual that are known to be associated with radiation exposure—such as radiation inducible malignancies (and, in theory, hereditary effects in the descendants of the exposed population)—cannot be unequivocally attributed to radiation exposure, since radiation exposure is not the only possible cause and biomarkers that are specific to radiation exposure are not generally available at present. These effects are so-called ‘stochastic’ effects. Thus, unambiguous differential pathological diagnosis is not possible for stochastic effects. Only if the spontaneous incidence of a particular type of stochastic effect were low and the radiosensitivity for an effect of that type were high (as is the case with some paediatric thyroid cancers) could the attribution of an effect in a particular individual to radiation exposure be ostensible, particularly if that exposure were high. Even then, however, the effect in an individual cannot be attributed unequivocally to radiation exposure, owing to competing possible causes. In sum, an increased incidence of stochastic effects in a population could be attributed to radiation exposure through epidemiological analysis—provided that, *inter alia*, the increased incidence of cases of the stochastic effect were sufficient to overcome the inherent statistical uncertainties. In this case, an increase in the incidence of stochastic effects in the exposed population could be properly verified and attributed to exposure. It is to be noted that, although demonstrated in animal studies, an increase in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure. One reason for this is the large fluctuation in the spontaneous incidence of these effects. In some

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<sup>9</sup> The term *lawsuit* is used to mean proceedings by a party or parties with a *legal imputation* to another in a civil court of law.

jurisdictions, the radiation harm from stochastic effects could be *collectively* (but not individually) imputed to the situation, perhaps as a *class action lawsuit*.<sup>10</sup>

- Specialized bioassay specimens, such as some haematological and cytogenetic samples, that indicate biological changes attributable to radiation exposure can be diagnosed in exposed individuals by qualified *radiobiologists*. These can be used as biological indicators of radiation exposure even at very low exposure levels. It is to be noted, however, that the presence of such biological indicators in samples taken from an individual does not necessarily mean that the individual would experience health effects due to the exposure. It is not clear whether ‘harm’ can be imputed in these cases.
- There has recently been an international agreement that radiation health effects are not attributable situations involving low doses (e.g. doses similar to typical natural background doses), but that radiation risks could still be inferred from these situations, which can only be subjective conjectures. In sum, increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of average global background radiation levels. This is because of the uncertainties associated with the assessment of risks at low doses, the current absence of radiation specific biomarkers for health effects, and the insufficient statistical power of epidemiological studies. There is international consensus that the numbers of radiation induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels can not be estimated by multiplying very low doses by large numbers of individuals. These situations are very common in practice and legal imputation of radiation harm hypothetically assigned to them is controversial. It has been noted that public health bodies need to allocate resources appropriately, and that this may involve making projections of numbers of health effects for comparative purposes. This method, though based on reasonable but untestable assumptions, could be useful for such purposes if it were applied consistently, the uncertainties in the assessments were taken fully into account, and it were not inferred that the projected health effects were other than notional.

### 7.3 From Estimating Effects to Imputing Harm

The legal imputation of radiation harm has generated controversy over the years while avoiding a universal resolution. The issue can be summarized as follows:

- (a) Ascribing health effects to radiation exposure situations;
- (b) Attesting their occurrence by qualified experts;
- (c) Proceeding with legal actions such as imputation first and eventually charging, suing, indicting, prosecuting and judging, according to the legal practice

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<sup>10</sup> The term *class action lawsuit* is used to mean a lawsuit where one of the parties is a group of people which is represented collectively by a member of that group.

in the applicable jurisdiction. The matter seems to be particularly difficult in situations involving low individual radiation doses.

While the origin of the issue can be traced back to the times of multiple nuclear weapons tests, it was revitalized in the aftermath of large nuclear accidents, such as those at the nuclear power plants of Three Mile Island, Chernobyl and Fukushima Daiichi, and by the relatively recent interest in the so-called ‘misadministration’ of radiation doses in medical practices such as radiotherapy and radiodiagnostics.

The debate heated up in the aftermath of the accident at the Chernobyl nuclear power plant and was first reported in the 1993 Symposium on Nuclear Accidents: Liabilities and Guarantees convened by the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA).<sup>11</sup> At that meeting, the dilemma of causation associated with the radiological health consequences of the Chernobyl accident was addressed.<sup>12</sup> A decade after this initial debate, the influence of the issue in nuclear law was already a subject of discussion in legal literature.<sup>13</sup>

Thus, concerns were expressed early on about the epistemological constraints of attributing health effects to radiation exposure involving relatively low doses and its legal consequences. Notwithstanding these concerns, notional effects were being attributed to low radiation doses from the aftermath of the accident, not only in the refereed scientific literature,<sup>14</sup> but more noticeably at the academic level (e.g. in the *Annals of the New York Academy of Sciences*).<sup>15</sup> These opinions were in contradiction with estimates being reported by international organizations.<sup>16</sup> These contradictions caused serious concerns among members of the public and their representatives.

Unsurprisingly, following the accident at the Fukushima Daiichi nuclear power plant, the same type of reporting of unprovable effects became fashionable in scientific literature.<sup>17</sup> The reports were in full contrast with the scientific estimates by international organizations.<sup>18</sup>

Thus, the experts’ controversy on the health effects of low level radiation has been at the centre of a confusing and puzzling debate. Not surprisingly, the legal response to cases involving exposure to relatively low radiation doses has been ambiguous: while legal claims were generally unsuccessful in most countries in the past years, a number of cases have been successful, particularly in Japan, and these might have numerous legal implications.<sup>19</sup>

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<sup>11</sup> OECD/NEA 1993.

<sup>12</sup> González 1993, p. 25.

<sup>13</sup> González 2002.

<sup>14</sup> See, for example, Cardis et al. 2006.

<sup>15</sup> Yablokov et al. 2010.

<sup>16</sup> IAEA 1996; UNSCEAR 2008.

<sup>17</sup> See, for example, Ten Hoeve and Jacobson 2012.

<sup>18</sup> UNSCEAR 2013; IAEA 2015; González et al. 2013.

<sup>19</sup> See for example <https://www.bbc.com/news/world-asia-38843691>. Accessed 11 October 2021.

The equivocal treatment of the issue and the surrounding legal ambiguity are predictably causing bewilderment among the general public and favouring sensationalism in the media, and have already cost a high price in terms of public fear of low dose radiation.<sup>20</sup> As a result, in a number of cases, the regulatory processes for preventing low level radiation exposure in order to avoid legal implications have imposed severe penalties on society and, unwittingly, hindered the utilization of beneficial practices involving radiation exposure.

Perhaps the problems first arose as a result of misinformation and miscommunication between legal experts and an inhomogeneous group of radiobiologists, radioepidemiologists, radiopathologists and radioprotectionists. Moreover, communication with the public and its political representatives has been far from good. These mishaps have been discussed amply,<sup>21</sup> but no solution has been found.

A major legal conundrum is how to handle the epistemological miscalculation in the attribution of radiation effects to exposure situations where these effects could be conjectured but are not provable. This problem has been sufficiently discussed in the literature,<sup>22</sup> but over the years it seems to have been ignored both in regulations and in the legal practice.

An important effort to address the issue was carried out by the International Labour Organization.<sup>23</sup> A report was issued on approaches to the attribution of detrimental health effects to occupational ionizing radiation exposure and their application in compensation programmes for cancer. Although limited in its scope (it just covered occupational exposure and focused on compensation), this was a significant attempt to make advances on the issue of imputation. The document, recalling ILO Convention No. 115, requires that workers who have developed cancer as a result of occupational exposure to radiation are compensated, recognizes that a process of compensating for the disease must be selected that is capable of distinguishing between those cases most likely to have been caused by occupational exposure and background cases that have developed due to other reasons.

Fortunately, however, an international intergovernmental consensus on the attribution of provable radiation health effects vis-à-vis the inference of conjectured risk has been achieved relatively recently. This important step was finally reached a few years ago by UNSCEAR.<sup>24</sup>

In 2012 UNSCEAR refined the understanding of this paradigm by addressing the attribution of health effects to radiation exposure and the inference of risks.<sup>25</sup> UNGA unanimously welcomed with appreciation this scientific report by UNSCEAR.<sup>26</sup> The UNSCEAR estimates have been summarized by the United Nations Environment Programme (UNEP) in a booklet, whose main relevant findings and illustration are

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<sup>20</sup> Waltar et al. 2016.

<sup>21</sup> IAEA 2018.

<sup>22</sup> González 2011.

<sup>23</sup> ILO et al. 2010.

<sup>24</sup> UNSCEAR 2012.

<sup>25</sup> Ibid.

<sup>26</sup> UNGA 2012.

used in this chapter.<sup>27</sup> This important global agreement was reported widely in the literature,<sup>28</sup> but it is still far from being implemented in regulatory practice. The Commission on Safety Standards (CSS) has been addressing the issue and a report is in preparation (the CSS is the international body endorsing the international safety standards being established under the aegis of the IAEA with the co-sponsorship of all relevant international organizations).

After a long journey it seems that the scientific community has under UNSCEAR reached a consensus on health effects at low doses: risk can be inferred but actual effects cannot be attributed. This important scientific consensus should now be converted into legal instruments that address the issues of imputation, suing, prosecuting, charging, indicting and judging, following radiation exposure situations. A discussion on the transit from scientific attribution and inference to legal imputation (and therefore to suing, prosecuting, charging, indicting and judging) followed these developments,<sup>29</sup> but has not yet crystallized in universal approaches.

## 7.4 The Fundamental Paradigm

This renewed UNSCEAR paradigm<sup>30</sup> is subtly more precise than previous estimates<sup>31</sup> that are currently used by international intergovernmental regulations to protect people against the detrimental effects of exposure to radiation,<sup>32</sup> and consequently, by the vast corpus of nuclear safety regulations. For instance, the current regulations do not make clear distinctions between attribution of factual effects and inference of conjectured risks. However, the renewed international paradigm provides the scientific and regulatory foundation for the legal issues associated with the imputation of harm to radiation exposure situations.

The paradigm can be simplistically summarized in an annotated dose-response relationship (see Sect. 7.4.1).

### 7.4.1 *The Dose-Response Relationship*

The relationship between the radiation doses incurred by people and the probability of occurrence of health effects (so called, *dose-response relationship*), which can be derived from the UNSCEAR estimates, has been synthesized by UNEP in the graph shown in Fig. 7.1.<sup>33</sup>

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<sup>27</sup> UNEP 2016.

<sup>28</sup> González 2014b, c.

<sup>29</sup> González 2014a.

<sup>30</sup> UNSCEAR 2012; ICRP 2005.

<sup>31</sup> UNSCEAR 2008.

<sup>32</sup> IAEA 2014; ICRP (2007) 2010.

<sup>33</sup> UNEP 2016, p. 25.



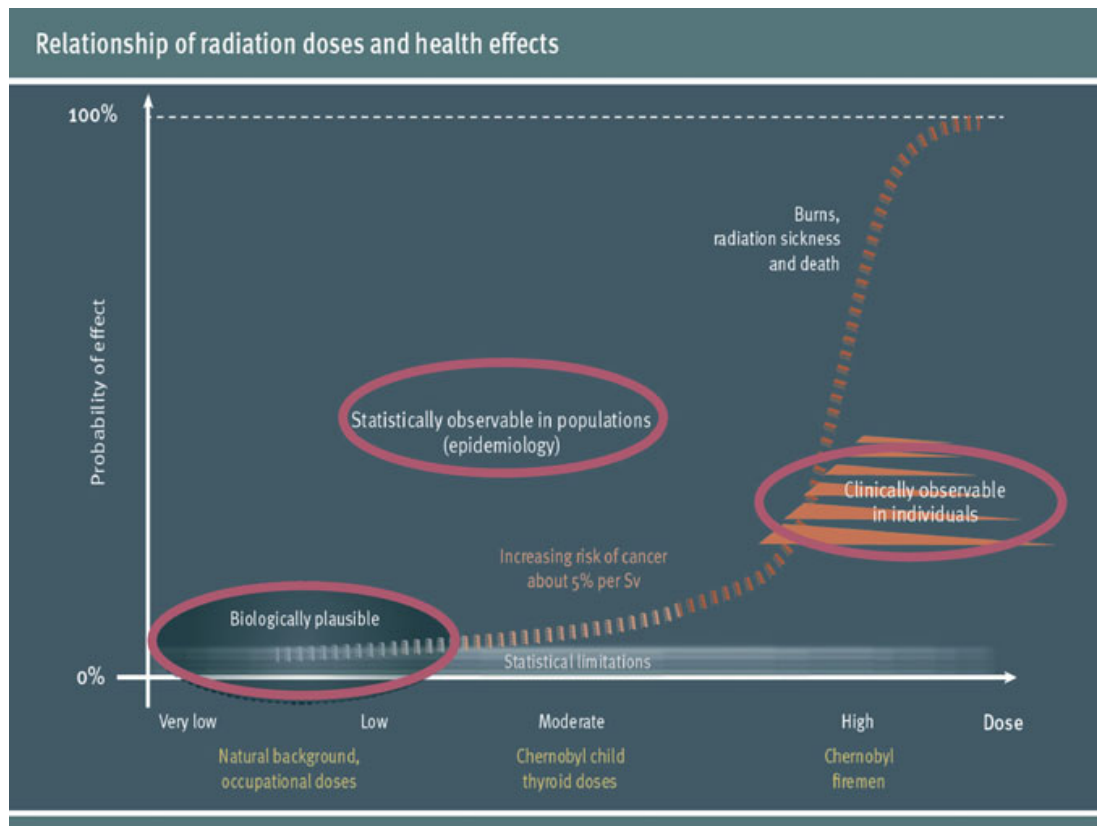


Fig. 7.1 The dose-response relationship. Source UNEP 2016, p. 25

The doses are expressed as:

- ‘*High doses*’ (around a ‘sievert’ of effective dose [note that the average natural background dose is 0.0024 sieverts per annum, therefore one sievert is thousands of times higher than the annual levels of natural background radiation]);
- ‘*Moderate doses*’ (around hundreds of thousandths of sievert [a thousandth of a sievert is termed ‘millisievert’]);
- ‘*Low doses*’ (about tens of millisieverts);
- ‘*Very low doses*’ (around a millisievert).

The probabilities are expressed in percentages of between 0 and 100%, where:

- 100% corresponds to the certainty that *the effect will occur*;
- 0% corresponds to the certainty that *the effect will not occur*.

It is to be noted that the probabilities estimated by UNSCEAR are of two distinguishable types:

- *Frequentist probabilities*, which are in the high dose area, based on the truthful and verifiable existence of radiation health effects, and are defined as the limit of the relative frequency of incidence of the effect in a series of certifiable epidemiological studies;

- *Subjective probabilities* (also called ‘Bayesian’), which are in the low dose area, are expressed as a possible expectation that radiation health effects might occur, and are quantified by a personal belief or expert’s judgement that is not substantiated by the frequency or propensity that the effects actually occur.

Both frequentist and subjective probabilities are mathematically compatible but epistemologically very different: the former is based on *fact* and the latter is based on *conjecture*.

UNSCEAR has highlighted the importance of distinguishing between:

- *Verified observations of health effects* in exposed individuals and populations, which allow such effects to be unambiguously attributed to the exposure situations that generated them;
- *Theoretical projections of health effects*, for which occurrence is feasible but not verifiable—namely those projections only allowing some inferring of risks.

For both situations, it is important to take into account both the uncertainties and the inaccuracies associated with the estimates.

Given the current state of knowledge, certain effects on the health of specific people exposed to radiation, the ‘*deterministic effects*’, can be attributed with confidence if they were diagnosed by a specialist. These effects are usually acute and occur early in individuals exposed to high doses of radiation. They are termed deterministic because they are determined to occur if the dose exceeds a certain threshold value that has already been deemed to be a high dose.

It is also possible to attribute to radiation increases in the normal incidence of certain effects in populations, the ‘*stochastic effects*’ (e.g. increases in the incidence of cancers, which have been observed in populations exposed to high doses). These effects can manifest themselves in certain cohorts exposed to moderate and high doses of radiation, and appear after long periods of latency. They can be attributed to exposure by observing their incidence in affected populations, but only if the observed change in the base incidence of the effects is high enough to overcome statistical and epistemic uncertainties. Owing to the randomness of their appearance, they are called ‘*stochastic effects*’. The probability of occurrence of stochastic effects is calculated on the basis of the measured frequency of the effects, and it is generically termed ‘risk of radiation’, or simply ‘risk’; such risk is usually expressed as a dimensionless number per unit dose of radiation incurred.

Currently there are no biomarkers available to distinguish whether a stochastic effect in an individual has been caused by exposure to radiation or by another cause, or is simply a natural occurrence. That is, there are no biological specimen standards that allow for specific diagnoses of stochastic effects in individuals. For this reason, stochastic effects are not attributable to the exposure incurred by specific individuals, but only to the collective exposure incurred by a population. Here they are expressed as a change in the base incidence of the effect.

No changes have been confirmed in the incidence of health effects, in situations in which the level of exposure to radiation is low or very low (e.g. in typical situations of exposure to environmental and occupational radiation). Among other reasons, the

statistical and epistemic uncertainties of epidemiological studies at low and very low doses make this confirmation impossible.

Notwithstanding this, the silent occurrence of such effects cannot in principle be discarded and a probability might be assigned to such hypothetical occurrence. Thus, *the probability that stochastic effects occur at low and very low doses can only be inferred subjectively through expert judgements*. Therefore, at low and very low doses, it is necessary to make assumptions and use mathematical models to estimate a subjective probability of the occurrence of health effects, which leads to results that are uncertain. This subjective probability is also often referred to as ‘risk’.

Consequently, for low and very low radiation doses, UNSCEAR has chosen not to use such mathematical models in its evaluations for projecting numbers of radiation health effects (or even deaths), owing to the resulting unacceptable uncertainties that are intrinsic to the predictions. However, UNSCEAR estimates that these calculations can be applied to make suppositions that can be used for public health comparisons or for radiological protection purposes, provided—as UNSCEAR has warned—that uncertainties are taken into account and limitations are clearly explained.

In summary, as marked with ovals in Fig. 7.1, UNSCEAR made a clear distinction between three separate regions of the dose-response relationship, in relation to the observance of the effects, namely:

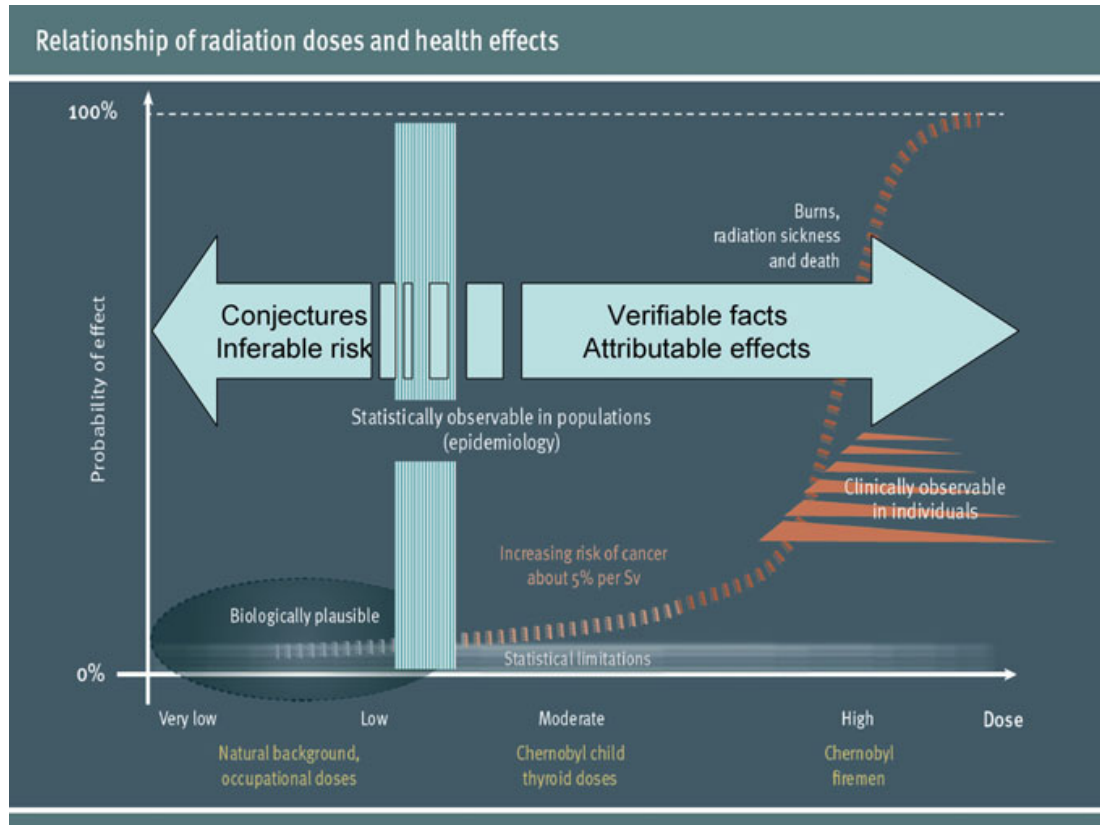
- The region where the effects are clinically observable in individuals, through a radiopathological diagnosis and attestation by certification;
- The region where the effects are only statistically observable in populations (but not identifiable in individuals), through radioepidemiological estimates and attestation or certification;  
(in both of these situations the available probabilities are frequentist),
- The region where the effects are not observable but can be biologically plausible, and can only be inferred through the subjective judgement of experts (i.e. subjective probabilities are only possible here).

## 7.5 Verifiable Facts Vis-à-Vis Subjective Conjectures

It follows from the previous discussion on the paradigm that the abscissa of the dose-response relationship, which quantifies the dose, can be divided into two distinguishable areas, as presented in Fig. 7.2 and described in this section:

- Doses that lead to effects resulting from objectively verifiable facts, that is, truthful instead of interpretable events, those that take place indisputably and are not influenced by personal feelings or opinions;
- Doses that only lead to subjective inferences based on conjectures, that is, on opinions or conclusions based on incomplete information not proven and perhaps influenced by personal feelings or opinions.

It follows that the two distinguishable areas are:



**Fig. 7.2** The abscissa of the dose-response relationship divided into two distinguishable areas. Source UNEP 2016, p. 25 (adapted)

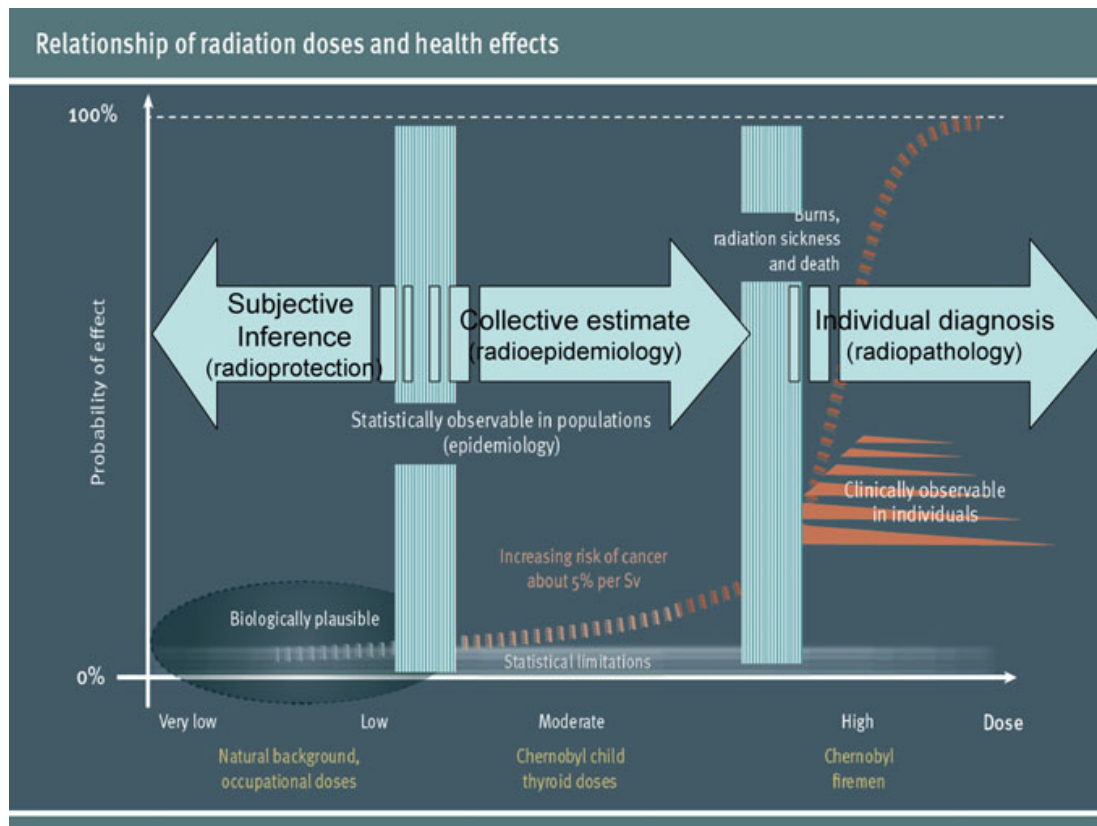
- The area where it is feasible to attribute effects objectively to radiation exposure situations;
- The area where it is not feasible to attribute effects objectively, although there is the possibility of inferring risks subjectively.

## 7.6 Attestation

As discussed previously, the attestation of occurrence of radiation effects can be done by radiopathologists for determinist effects in individuals and by radioepidemiologists for stochastic effects on populations. Attestation is not feasible when only expert judgement exists.

The area of the dose-response relationship where the effects are attributable can still be divided into two sub-areas, as follows and as shown in Fig. 7.3.

- In the high dose region, the occurrence of the effects can be *diagnosed* in the exposed individuals.
- In the moderate dose region, only changes in the incidence of effects in exposed populations can be assessed, usually by statistical calculations, namely estimated throughout *epidemiological* studies.



**Fig. 7.3** Sub-areas of dose-response relationship where the effects are attributable. *Source* UNEP 2016, p. 25 (adapted)

- In the low and very low dose region, there is only the possibility of *expert judgement* and an extrapolation of knowledge, but there is no possibility of individual diagnosis in the exposed person or of determinations of changes in the collective incidence of effects in the exposed populations by epidemiological studies.

Therefore, a further distinction is possible in the attribution of effects, as presented in Fig. 7.3:

- In the area of the high dose zone, the effects can be attributed individually, that is, it can be diagnosed and attested by pathological procedures that an exposed individual has incurred the effect;
- In the area of the moderate dose zone, the effects can be estimated collectively, that is, it can be evaluated if there is an increase in the incidence of effects in an exposed population, although it is not feasible to diagnose these effects individually;
- In the remaining area of the low dose zone, the effects cannot be attributed, either individually or collectively, although a ‘risk’ can be inferred expressed as a subjective probability that is not based on measurable frequencies but on personal judgements of experts or regulatory decisions.

As shown in Fig. 7.3, the process requires different professional attestations, as follows:

- Individual attribution of effects can only be made through a diagnosis followed by a certificate of formal attestation issued by a qualified *radiopathologist*;
- Collective attribution of effects can only be done by statistical estimation followed by a certificate of formal attestation by a qualified *radioepidemiologist*;
- Subjective inference of effects might require a consensus opinion of a professional body of relevant specialists, mainly radiobiologists and radioepidemiologists acting as radioprotectionists, who must express their ‘expert judgement’ about the risks, if any, as well as their uncertainties and limitations; such judgement should be validated by regulatory decisions.

## 7.7 Legal Consequences

The ability to attribute health effects to specific exposure situations can influence the capability to legally impute damages by those who suffered the effects. The imputation may include assigning liabilities for physical injuries or harmful effects deliberately inflicted on those who cause exposure. For example, workers can impute their employers; members of the public can impute licensees of installations operating in their habitat. However, the legislation related to the attribution of radiation health effects, to the inference of radiation risk and, in particular, to the imputation of damage is inhomogeneous, incoherent and inconsistent among countries as well as in cases held in jurisdictions within a country. An important distinction results from comparing jurisprudential legislation with codified legislation.

The noun *imputation*, the verb *to impute* and its gerund *imputing* are all of very common usage in many legal jurisdictions (e.g. in legal regions of Ibero–America). However, the usage of imputing is not so common in some legal cultures (e.g. in some Anglo–Saxon jurisdictions). Imputation and its derivatives are grammatically correct, as they mean attributing something bad (in this case something bad caused by radiation exposure) to someone (e.g. to employers by radiation exposed workers, or to radiation-related operators by affected members of the public). In sum, imputing means ascribing guilt to someone, be a real or a legal person.<sup>34</sup> Other related terms are used for similar legal purposes, including the following: *suing and prosecuting*, which refer to the institution of legal proceedings following radiation exposure; *charging*, which refers to the formal accusation of a law offence (e.g. violating radiation protection regulations); *indicting*, which is used to mean formally accusing of a crime (e.g. killing a person with radiation); and, of course, *judging*, which is used to mean giving a verdict by a public officer appointed to decide cases in a law court. It is underlined that the descriptions in this chapter are applicable *mutatis mutandis* to any of these concepts.

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<sup>34</sup> The term is derived from the Latin *imputare* meaning to ‘enter in the account’.

### 7.7.1 *Jurisprudential (Case-by-Case) Legislation*

Case-by-case legislation based on jurisprudential hermeneutics is distinguished from codified statutory legislation by its flexibility. This legislation can easily deal with situations involving deterministic effects and it is malleable to interpret probabilistic situations such as the damage attributable or inferable following radiation exposure at moderate, low and very low doses.

For example, in some countries where this type of legislation prevails, the concept of *assigned share*<sup>35</sup> has been used to settle cases of imputation owing to radiation damage due to stochastic effects.

The *assigned share* is equal to the fraction of the total number of cases of a specific type of cancer diagnosed among individuals that is in excess of the baseline number of cases for persons who share the same attributes, such as absorbed organ dose, age, time since last exposure, sex, smoking history. The assigned share is quantified as the relation between the *excess relative risk* and the *relative risk*.<sup>36</sup> The *assigned share* is often referred to as the ‘attributable fraction’ or ‘probability of causation’ assuming that the calculated excess relative risk represents the net consequences of mechanisms of disease manifestation for a given individual diagnosed with disease.

### 7.7.2 *Codified Legislation*

Many legal systems in large regions (e.g. in Ibero–America) have ‘codified’ legislation, namely legislation following the process of compiling and reformulating the law, generally by subject, forming a legal code, that is, a codex of the law. The movement towards codification gained momentum during the Enlightenment and became widespread after the promulgation of the Napoleonic Code.

The codified legal system prevents arbitrariness and discrimination, which was years ago relatively widespread in authoritarian monarchical regimes. However, it must be recognized that a codified legal system is fundamentally a deterministic system, a system which is predetermined by the codification.

Therefore, the codified legal system is tailored to deal with exposure situations leading to deterministic effects, given that there are dose thresholds that define whether an effect is determined to occur or not, namely whether it is attributable

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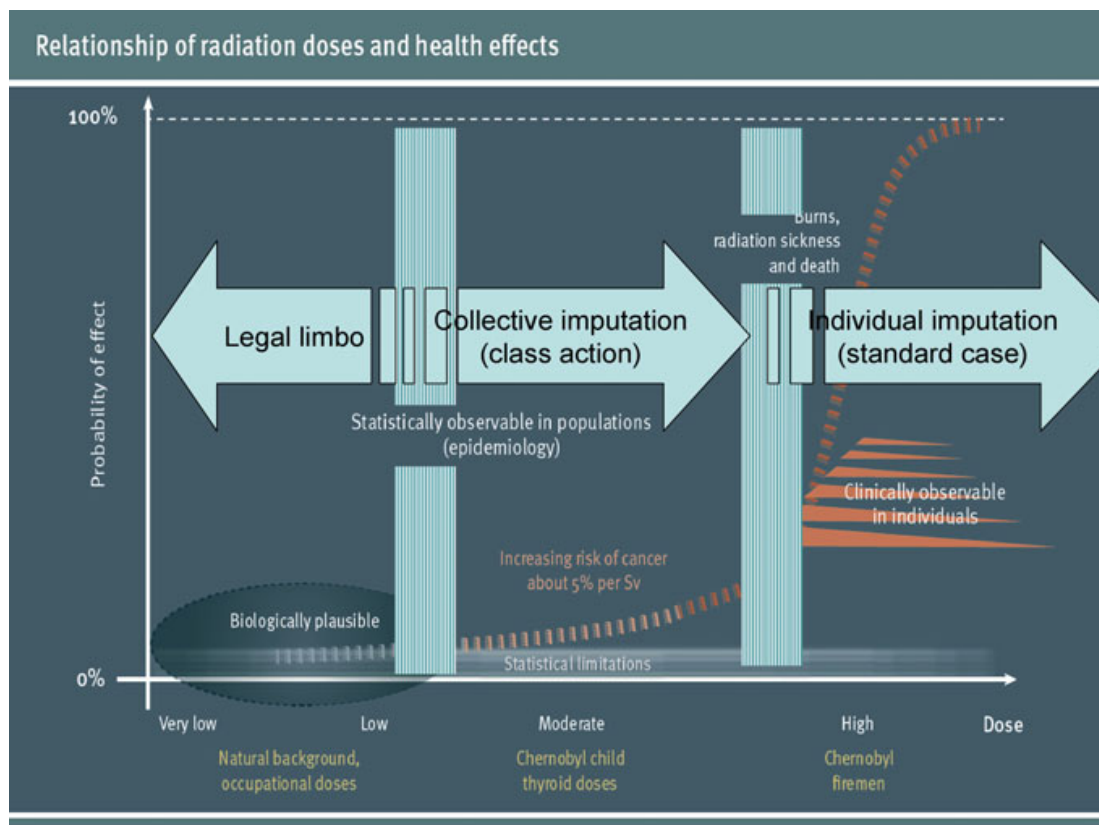
<sup>35</sup> *Assigned share* is used to mean the probability that an observed health effect (either deterministic or stochastic) in an individual was caused by a specific radiation exposure.

<sup>36</sup> *Relative risk* is used to mean the ratio of disease rates in different groups (e.g. an exposed and unexposed group) or for different exposure conditions (e.g. people exposed at high dose rates and people exposed at low dose rates); it is often useful to view the relative risk as a function of variables, such as dose, sex or age (it is noted that while this ratio is commonly called a relative risk, this is a misnomer; it is actually a ratio of rates, as are statistics derived from it); strictly, while the ratios involved are statistically calculated from observed frequencies/rates, the excess relative risk is a prospective estimate inferred from the data and reasoning. *Excess relative risk* is used to mean the *relative risk* minus one, and it is often considered as a function of dose and other factors.

or not. The effect occurrence can be attested unambiguously by a competent expert with credentials in radiopathology and since penalties can be codified, the imputation becomes straightforward. But the system is not completely tailored to deal with probabilistic situations, especially situations of low probability, such as those related to the possible damage of radiation exposure where the probabilities are not even sustained by factual frequencies of occurrences but are just an ‘experts’ subjective judgement’, which is not tailored to codification. The codified legislation is therefore problematic to solve cases of imputation of stochastic effects.

### 7.7.3 *Individual Imputation Vis-à-Vis Collective Imputation Vis-à-Vis Fictional Imputation*

The imputation of harm associated with radiation exposure continues to be a legal conundrum. It might be simpler to resolve in jurisprudential, case-by-case legal systems but it is particularly cumbersome for codified legislation where case-by-case approaches are not feasible. As presented in Fig. 7.4, the following situations are possible:



**Fig. 7.4** Schematic representation of the ability to impute following different radiation doses is presented. *Source* UNEP 2016, p. 25 (adapted)



- In the high dose region, the imputation is direct from the affected individual to the culprit.
- In the middle dose region, it would seem that only a collective or group imputation is feasible.
- In the low dose region, the situation is at least questionable. Is it possible to impute perceived consequences owing to radiation risks based on subjective judgements?

In the high-dose region, individual health effects are clinically attributable and attestable, and imputation of harm from the affected individual is therefore feasible. In the middle dose region, increased incidences of harmful effects in population groups are epidemiologically attributable and attestable, and imputation from the affected group is therefore feasible. In the low dose area, where radiation harm is neither attributable nor attestable, neither individually nor collectible, but also radiation risk might be inferred, the situation seems to be in a legal limbo.

## 7.8 Conclusion

After a long journey it seems that the scientific community has reached under UNSCEAR a consensus on the attributability of harm to radiation exposure situations. This important scientific consensus should now be converted into legal instruments that address the issue of legal imputation, and its derivatives of suing, prosecuting, charging, indicting and judging, following radiation exposure situations. While, following these developments, the transit from scientific attribution and inference to legal imputation has been preliminary discussed,<sup>37</sup> it has not yet been crystallized in universal approaches.

The time now seems to be ripe for legal experts to convert into legal guidance the scientific achievements on attribution of radiation effects and inference of radiation risks following radiation exposure situations.

Given the cultural, regulatory and legislative differences among countries, it is considered prudent and necessary to address internationally this legal issue with two fundamental objectives:

- (a) Fostering a common legal understanding on policy related to radiation harm attributed to radiation exposure situations;
- (b) Exploring the feasibility of a universal legislative interpretation to regulate the application of the law in these situations, which might serve as a potential input to different national legislations.

The onus is now on the legal experts on nuclear law.

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<sup>37</sup> González 2014a.

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