Basis for Regulatory Requirements for Design and Safety Analysis of NEW Reactor Facilities

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**Abstract**

This paper evaluates the requirements and criteria for safety analysis in applying risk-informed decision-making to new reactor designs such as Small Modular Reactors (SMRs). The focus is on high-level objectives, asserting that risks posed by a nuclear facility should be comparable to those normally encountered by the public and lower than those from alternative power generation methods. The current dose criteria and safety goals used in safety assessments are argued to be not suited for the range of designs, sizes, and concepts of SMRs under consideration. These criteria primarily aim to limit public radiation dose to a fixed level, regardless of reactor size or configuration; thus, impacting the effectiveness of risk-informed decision-making. The paper investigates key metrics and elements for comparative risk assessments to establish a benchmark for “reasonable risk” through modification of quantitative safety criteria. It emphasizes the importance of comparing reactor facility risks and benefits per unit of output against those of alternative energy production methods. Additionally, it identifies that cumulative risks from design basis accidents are not fully captured in current deterministic safety criteria. Based on the arguments presented, three recommendations are made to improve the risk-informed decision-making process.

# Introduction

## The Regulatory Challenges for Small Modular Reactors

With recent interest in the deployment of a variety of advanced NPP designs, particularly Small Modular Reactors (SMRs), regulators are challenged in safety assessment. The deterministic dose criteria and safety goals do not always translate well to smaller reactors and their deployment in multiple modules. The established criteria may not be applicable to all types of reactor facility. While the safety of nuclear energy must remain a priority, it is imperative that regulatory requirements be modernized as power generation technologies are changing.

It is therefore important to achieve a balance between the level of conservatism in nuclear regulations and standards to prevent *unreasonable risk* to the public and the environment against the benefits of nuclear generation to meet energy needs while reducing carbon emissions.

This paper identifies three major weaknesses in current regulatory requirements for reactor facilities that are shown to be inadequate when SMRs are considered. These issues arise in part from failure to fully implement IAEA-SF-1, *Fundamental Safety Principles*, principles 4, 5 and 6 in IAEA Safety Standards and Guides (e.g. IAEA SSR-2/1 Rev. 1, *Safety of Nuclear Power Plants: Design* and SSG-2 Rev. 1, *Deterministic Safety Analysis for Nuclear Power Plants*), Refs. [1, 2 and 3]. Three challenges are identified:

1. **Failure to ensure that risk is justified by benefit**: regulatory requirements do not typically assess the risk of a nuclear project against alternative means of achieving the project goal.
2. **Safety criteria are blind to size and number of reactors**: current regulatory safety criteria against which a construction licence is assessed are set "per reactor year".
3. **Safety criteria are blind to design complexity**: SMRs tend to be simpler and use passive features in comparison to large Nuclear Power Plants (NPPs).

## Regulation of Nuclear Power Generation

In the context of nuclear power generation, a comprehensive framework of national and international regulatory requirements and standards has been established. These standards, including quantitative and qualitative criteria, are to ensure nuclear reactor facilities do not pose an unacceptable risk to the public, workers, or the environment. There are variations in detailed requirements amongst regulatory bodies; however, at a high-level, these national safety objectives are coherent and are well represented by the IAEA Safety Fundamentals SF-1 and its supporting Safety Standards and Guides.

Safety requirements were developed primarily based on large, water-cooled reactor facilities. Innovations in generation technology, notably with SMRs, can challenge the underlying assumptions of the current set of requirements. These requirements focus mainly on protection of the public from the release of radioactive materials in normal operation and accidents in reactor facilities.

The IAEA Safety Standards and Guides, along with many national regulations, currently lack detailed requirements to compare the risk of nuclear power generation with alternative generation sources. These standards are clearly **sufficient** to ensure safety, but their requirements are not shown to be **necessary**. In particular, the detailed requirements may make excessive demands that are not supported by comparison of overall safety of the technology with alternative sources of generation.

This paper examines the hierarchy of objectives, qualitative and quantitative requirements to determine if current quantitative metrics fully reflect the underlying safety objective to ensure adequate protection of the public.

## Objectives

Regulatory dose acceptance criteria and probabilistic safety goals are typically set in accordance with the principle of limitation of risk to individuals without due consideration of a comparative analysis or reactor size. This gap leads to quantitative criteria that are not fully risk informed.

In this paper it is argued that, unless level of risk from a nuclear facility is compared to other forms of generation and normalized to reactor output, the current quantitative dose criteria do not fully reflect the intent of high-level safety objectives; and therefore, regulatory decisions may not be risk informed.

# Comparison of Risks and Benefits

To meet IAEA **SF-1, principle 4**, it is necessary to justify that the benefits of operating a nuclear facility outweigh the associated risks. Similarly, to meet IAEA **SF-1, principle 5** (para 3.24), “*the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control”*. These principles primarily focus on radiation health risks. Here, the focus must depart from the IAEA’s narrow focus on solely radiation risks.

To determine if risks to the public are reasonable, there must be an evaluation of risks posed by the facility in comparison to:

* risks to which people are normally exposed, and
* risks from alternative means of producing energy.

It is important to consider both large infrequent risks as well as minor yet frequent (or continuous) risks. While nuclear safety risk criteria include all these risks, they are not evaluated on a continuum.

* Safety assessments predominantly focus on DSA dose acceptance criteria and PSA safety goals, with particular emphasis on design basis accidents and severe accidents, respectively.
* Radiation protection regulations deal with continuous or frequent radioactive releases.

With discontinuous assessments, it is not possible to know whether rare, high consequence accidents pose a larger or smaller risk than the frequent low consequence releases.

This paper identifies major costs and benefits with no attempt to perform a full qualitative assessment. In the paper, existing published work is referenced where available. Such an assessment of costs and benefits must form part the licensing process for a reactor facility.

## Health Risks

Health risks associated with nuclear facilities can be divided into short-term accidental risks of death or injury and long-term stochastic effects[[1]](#footnote-1). Comparison of these short- and long-term effects may be carried out by using the years of life lost or impaired. Health risks can also be apportioned between facility workers and the general public. Facility workers have some degree of control over the risk and derive employment benefit; hence, tolerance for risk to the public is typically lower.

Justification and reasonableness of public risk is most clearly expressed by comparing the relative risks of generation of useable energy by various means. It is assumed that the benefits of the energy are the same for all forms of energy generation. This approach is also expected to be applicable to direct use of the energy output of the facility in industrial processes. For direct uses of energy, output can be converted to equivalent electrical generation.

Although the benefits from energy are similar for all forms of generation, the risks to health and safety, the environment, economy and society vary significantly depending on how it is generated. To simplify the comparison, the risk can be expressed as “risk of prompt or late fatalities per unit of electrical power sent out by a generating station”. Results from some studies are summarized below.

### Ritchie (2020) based on Markandya and Wilkinson (2007)

Ritchie (2020) [4] provided comparative death rates per terawatt hour (TWh) for different energy sources based on peer-reviewed publications, most importantly Markandya and Wilkinson (2007) [5].

The mortality rates reported by Ritchie include accidental deaths and pollution-related effects. The rates account for impacts from all stages of the fuel cycle, including fuel extraction, transport, transformation, waste disposal, and electricity transport. Data for fossil generation are based on data for Europe from Markandya and Wilkinson (2007). Ritchie’s analysis includes two major accidents not part of the earlier study: namely the 1975 Banqiao Dam Failure in China and the 2011 Fukushima Daiichi accident in Japan. Results from this study are summarized below in Table 1.

Table 1. Mortality Rate from Accidents and Pollution by Generation Source

| Electricity source | Deaths/TWh | Deaths normalised to nuclear | CO2 Emissions: tonne/kWh |
| --- | --- | --- | --- |
| Brown Coal | 32.72 | 1090.67 |  |
| Coal | 24.62 | 820.67 | 970 |
| Oil | 18.43 | 614.33 | 720 |
| Biomass | 4.63 | 154.33 | 78-230 |
| Natural Gas | 2.82 | 94.00 | 440 |
| Nuclear | 0.03 | 1.00 | 6 |
| Wind | 0.04 | 1.33 | 11 |
| Hydropower | 1.30 | 43.33 | 24 |
| Solar | 0.02 | 0.67 | 53 |

Neither the Ritchie nor the Markandya and Wilkinson results include the deaths due to climate change, which is discussed in Section 2.3 below.

Ritchie’s figures for CO2 emissions highlight the significant increase in public health risk with even a minimal integration of fossil-based generation in a country’s power supply compared to the use of low-risk sources (solar, nuclear or wind).

Our understanding of risks of power generation is constantly evolving. The scale of the risks from climate change are only recently becoming clear and are not fully integrated into risk evaluations.

Risks of alternative generation technologies need better quantification. For example, dam failures are increasing due to aging structures and inadequate maintenance. The United Nations University Institute for Water, Environment and Health report UNU-INWEH-11 *Ageing Water Storage Infrastructure: An Emerging Global Risk* [6] warns that “*tens of thousands of existing large dams have reached or exceeded an ‘alert’ age threshold of 50 years, and many others will soon approach 100 years.*” The report concludes that without very expensive maintenance or closure, the likelihood major accidents will increase. The problem is underlined by the September 2023 Derna dam collapse in Libya with the estimated death toll between 5,300 and 20,000 [7]. These deaths are not included in Table 1.

### Other Risks to Individuals and Society

Qualitative safety objectives can be found in IAEA SF-1 *Safety Fundamentals*, [1]. The SF-1 safety principles provide a qualitative target for assessing if risks are “reasonable”. In this paper, SF-1 Safety Principles 4, 5 and 6 are particularly relevant. Together, they require that **risks are: 1) outweighed by their benefits, 2) commensurate with the magnitude of risk, and 3) controlled through the establishment of limits to dose and radiation risk**.

Any additional risk to individuals and the public must be small in comparison to other risks present within society. Leading causes of death in OECD countries for 2019 are taken from Figure 3.7. of *Health at a Glance 2021*, OECD (2022) [8]. Cancer and accident fatalities are most relevant to discussions of risks from reactor facilities. Fatalities attributed to reactor facilities must not add significantly to these risks.

Table 2: Leading Causes of Death, OECD, 2019

| **Cause of Death** | **Deaths** | **%** |
| --- | --- | --- |
| All deaths (2019) | 11,390,721 |  |
| Diseases of the circulatory system | 3,464,538 | 30 |
| Cancers | 2,712,655 | 24 |
| Diseases of the respiratory system | 1,141,035 | 10 |
| Alzheimer's and other dementias | 977,813 | 9 |
| Accidents | 478,217 | 4 |
| Diabetes | 364,565 | 3 |

The current dose acceptance criteria for design basis accidents (DBAs) in a nuclear facility are established to ensure that no offsite protective actions are necessary – see paragraph 5.25 of IAEA SSR-2/1 Rev. 1, [2]. While this criterion may be reasonable for addressing the most frequent DBAs, there seems to be no scientific rationale for providing such level of protection against accidents that are less likely than major catastrophes caused by rare events such as earthquakes, extreme weather or major fires.

In comparison to nuclear facilities, other energy generation sources lead to offsite emergency measures at higher frequencies, e.g., flooding from hydro dams or gas leaks from pipelines. Applying **fixed dose criteria that span three or four decades of accident frequencies are not risk informed.**

## Loss of land

Beyond health risks, the loss of land due to power generation is one of the main societal effects that must be weighed when comparing the costs and benefits of different generation sources. Loss of land may be planned or unplanned. Planned land losses may include flooding a valley for a hydroelectric project, land lost for mining operations, or the establishment of uninhabitable exclusion zone around nuclear facilities or wind farms. These planned losses are typically considered as part of the regional land use planning, which considers societal factors such as the number of people who may require relocation and the loss of productive land. Unplanned loss of land, such as from a nuclear accident, oil spill or hydroelectric dam failure, as well from global warming phenomena, should carry more weight. Land loss has not typically been factored in the planning process for generation projects. Moreover, the effects extend across national or regional boundaries so that the costs are often borne by people who do not receive the benefit.

## Climate Change

Greenhouse gas emissions vary significantly across different energy sources, making comparisons difficult. While many publications have presented results on this subject, there can be significant variations in scope, methods and assumptions that can lead to different results. Nonetheless, a clear picture emerges – fossil fuels, particularly coal, release vastly more greenhouse gas than other forms of generation. This is clearly shown by the CO2 emissions given by Ritchie [4] and summarized in Table 1 in section 2.1.1. Nuclear and renewables are by far cleaner than all forms of fossil fuel generation. A more detailed comparison is available in the 2022 report by United Nations Economic Commission for Europe, *Carbon Neutrality in the UNECE Region: Integrated Life-cycle Assessment of Electricity Sources* [9]. This report covers a more detailed list of generation sources and includes comparative data on a range of environmental pollutants.

# Limitation of Public Risk

**IAEA SF-1 Principle 6** mandates that “*doses and radiation risks must be controlled within specified limits*”. In many countries, the highest-level quantitative safety standards are **deterministic dose criteria** and **probabilistic safety goals**. With the development of new and advanced reactor designs, it is becoming important to re-evaluate regulatory requirements to ensure that they are applicable to a wide range of facility designs and sizes. The regulatory requirements must be fully risk informed to strike a balance between risks and benefits.

In establishing requirements for the design of nuclear power plants (NPPs), adherence to IAEA Specific Safety Standard SSR-2/1 Rev. 1, [2], commonly leads to development of **deterministic dose criteria**, assessed through deterministic safety analysis (DSA), and safety goals, and verified through probabilistic safety (or reliability) assessment (PSA or PRA). These dose criteria and safety goals are normally based on mitigating different levels of offsite protective actions, such as sheltering, short-term evacuation or long-term relocation of the public.

Dose limits are normally expressed as release limits per reactor and take no account of reactor size or the existence of multiple reactors on a site. Limits are typically based on International Commission on Radiological Protection (ICRP) publications 103 [10] and 109 [11] recommended protective measures (e.g., sheltering or evacuation) if the averted dose is within 20 to 100 mSv/year range, with national authorities establishing the desired level of protection.

The deterministic dose criteria and safety goals, the basis for safety assessments, are derived from ICRP recommendations are based on the Linear, No Threshold (LNT) hypothesis for radiological risk. However, the LNT hypothesis is increasingly being viewed by radiation scientists as overly conservative or even potentially increasing public risk – see Sachs, Meyerson and Siegel, (2016) [12].

Probabilistic safety goals are normally set for core damage frequency and large release frequency. with the objectives to mitigate the risk from severe accidents. However, PSAs do not set safety goals to control the integrated risk of higher frequency, lower consequence events such as anticipated operation occurrences (AOO) and design basis accidents (DBA). While PSA can potentially calculate the risks of more frequent accidents, this capability is not commonly used.

Dose limits or dose acceptance criteria are commonly used to manage public risk for more frequent transients and accidents, including AOOs and DBAs. These criteria are set to limit the consequences of postulated bounding (worst-case) accidents. However, they do not control the **total number** of AOOs and DBAs; or integrate the **cumulative risk** over all AOOs and DBAs (see sub-section 4.2.3. Consequently, these simplistic dose criteria fail to distinguish complex facilities with many potential accidents from simpler facilities with fewer potential accident.

# Discussions

## Issues with Demonstration of “Unreasonable Risk”

In accordance with the IAEA SF-1, Safety Principle 4, risks from a nuclear facility must be justified by its benefits. This can be assessed through qualitative safety goals to ensure that the risks associated with a reactor facility operation should not significantly contribute to already existing risks, and they should be comparable to or lower than risks posed by alternative energy generation technologies.

Understanding what could be considered a ‘reasonable risk’ to which a population is exposed in everyday life, in OECD countries, cancer was the second highest cause of death at 21% in 2021 [13] for all types of cancer. With an average life expectancy at birth of 80.3 years, this implies that the average annual probability for a member of the OECD population to die from cancer is 0.21 / 80.3 = 2.616x10-3 /y.

To assess radiation risks, the ICRP Publication 103 recommends a risk coefficient for cancer of 0.055 Sv-1 [10]. This coefficient is based on the LNT assumption and is conservative, particularly at low doses. Applying the ICRP risk coefficient and a typical dose acceptance criterion of 20 mSv to the highest frequency DBA (widely agree to be 10-2 y-1) the estimated risk to the most exposed person can be calculated. The individual risk from such a dose would be: 0.055 Sv-1 x 0.02 Sv x 10-2 y-1 = **1.1 x 10-5 y-1**.

The above calculation gives a dose for the most frequent accident in the DBA range. It would increase the person’s lifetime risk of a fatal cancer from 2.616x10-3 to 2.627x10-3 y-1, an increase of 0.42%, i.e. it would increase the person’s risk of death from fatal cancer from 21% to 21.42%. While it is not negligeable, the increase in public risk is small (less than the typical annual variation). Thus, at the high-frequency end of the DBA frequency range, such a change in risk is in keeping with the qualitative safety goal objectives. However, at the low frequency bound of the DBA range[[2]](#footnote-2), the risk would be increased from 21% to 21.00042%, which is insignificant and greatly exceeds the objective of the qualitative safety goals. Application of a limit that is reasonable for 1-in-100-year accidents to 1-in-100,000-year accidents is therefore not risk informed.

## Issues with Quantitative Safety Goals

### Probabilistic Safety Goals

In general, the numerical safety goals are set “per reactor” and take no account of reactor size. Introducing additional safety goals “per plant” would partly address the issues related to modular plants; however, a careful definition of what constitutes a “plant” would be needed.

Setting site-based safety goals should maintain a balance between cost and benefit, though it is complicated by various confounding factors. One challenge is the sharing of the “risk budget” between different plants on a site, which may include older plant designed to earlier standards.

A further complicating factor is focusing solely on radiation risks. Site or location-based safety goals may prevent adding a new reactor adjacent to an existing plant as the local “risk budget” may already have been taken by the older facility. However, siting next to a chemical plant or other industrial facility is not factored in the radiation risk. In such a case, the risk to the local population from the industrial facility (e.g. chemical leaks, increased transportation risks, etc.) may be higher than that from older nuclear plant.

### Deterministic Dose Criteria

In many countries the deterministic dose criteria are implemented as dose limits for the most exposed individual during any single accident (AOOs and DBAs). Deterministic regulatory dose criteria for accidents less frequent than DBAs are not typically established, since risks from beyond design basis accidents are adequately controlled by PSA safety goals.

A weakness of setting the DSA dose limits for single accidents is that it fails to account for the cumulative risk of such postulated accidents. Typical DSA dose criteria such as those set in accordance with section 4.5(a) of IAEA Specific Safety Guide SSG-2 Rev. 1, *Deterministic Safety Analysis for Nuclear Power Plants* [3]. These criteria are very conservative at low frequencies and are not risk informed.

### Cumulative Risk

In this paper cumulative risk means “the sum of frequencies of all events whose outcomes exceed a defined consequence.”

To address the limitation of DSA dose criteria’s inability in controlling the total number of accidents within the design basis, additional criteria are necessary to restrict the cumulative risk. One approach is to set a probabilistic safety goal to limit the **integrated** risk in AOO and DBA.

Cumulative risk forms part of the US Licensing Modernization Program documented in NEI Technical Report 18-04 Revision 1, *Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development*, [14].

NEI-18-04 adds a new cumulative risk metric to manage risk from high-frequency, low-consequence events in addition to the PSA safety goals for severe accidents. As explained in NEI 18-04 section 3.2.2, this metric considers the consequences over the entire range of Licensing Basis Events.

### Reactor Size and Configurations

IAEA principle 4 of SF-1 states that “*benefits that [facilities] yield must outweigh the radiation risks to which they give rise...*” Also, IAEA SF-1, principle 5 that states: “*the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control.”* Dose criteria set ‘per reactor’ do not balance risks and benefits and are not commensurate with risk. For instance, a modular facility with 10 reactors could, in principle, be subject to an AOO event in each reactor during the life of the facility, potentially increasing the public dose from AOOs by a factor of 10. Despite having a comparable power output, such a 10-module SMR could pose significantly higher risks unless the dose criteria are set based on output. Similarly, single-module SMRs have the same release criteria as a large NPP but with proportionally smaller benefit.

Deterministic dose criteria, based on limiting the risk to an individual from an AOO or DBA, do not consider the associated benefit of the reactor facility. Additionally, they limit the dose that can be released without consideration of the reactor size. A small reactor may release a greater fraction of its radioactive material than a large reactor without considering that many small units would be needed to obtain the same benefit (electrical output) as a large facility.

# Conclusions and Recommendations

Licensees (or operators) of nuclear facilities have the responsibility to demonstrate that risks posed by reactor facilities to the health and safety of persons, and to the environment, are acceptably low. The nuclear regulatory bodies have the responsibility to verify that this demonstration meets regulatory requirements. However, the current approach of limiting risks with no consideration of the benefits impacts the effectiveness of decision-making approaches.

The dose criteria and safety goals currently used to perform this assessment are not well suited to the wide range of designs, sizes and concepts of SMRs currently under consideration. They are largely set to limit radiation dose to the public to a fixed level, without regard to reactor size or configuration; therefore, this has a negative impact on the effectiveness of risk-informed decision making.

Based on the analysis presented in this paper, the following recommendations are made to improve the effectiveness of the risk-informed decision-making process:

1. Balance risks with benefits:
	1. Risk criteria should be set in terms of energy output rather than solely “per reactor”.
	2. Risks posed by reactor facilities should be compared to those associated within other viable methods of generating electrical power.
2. Introduce cumulative risk targets:
	1. A cumulative risk target or safety goal should be established to account for the overall risks posed by the number of postulated accidents within the design basis.

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1. Stochastic health effects are those that occur by chance, and whose probability is proportional to the exposure, but whose severity is independent of the exposure. [↑](#footnote-ref-1)
2. There is no international consensus on DBA lower frequency. EU states typically use 10-6 /y and the US uses 10-4 /y. [↑](#footnote-ref-2)