CHAPTER 16

Regulatory Requirements and Licensing

prepared by

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Summary:

This chapter covers the overall aspects of nuclear reactor regulation, with emphasis on Canada, but also covering other regimes such as the United States, the United Kingdom, and Europe. It explains the need for regulation; how regulators work; how they are structured; and the types of requirements they set. Canada, the United States, and the United Kingdom are used as specific examples in these areas, with detailed material on Canadian licensing processes, requirements, and guides.

Disclaimer: *This Chapter captures the elements of nuclear power reactor regulation as of ~2013, when the Chapter was drafted. Although regulatory concepts change slowly, detailed licensing requirements can change fairly frequently, and some of the details in this Chapter could be superseded by the time the book is used. The reader is advised to consult the most up-to-date regulatory documents if the intended use at the time is critical. The information in this Chapter is current as of late 2012 or early 2013.*

Table of Contents

List of Figures

List of Tables

1 Introduction

The purpose of this chapter is to:

1. describe the need for, and concepts underlying, nuclear regulation
2. cover specific requirements in Canada in some detail, and examples from other jurisdictions where the differences are instructive.

Whereas the first aspect covers "why", the second aspect covers both "why" and "what".

1.1 Overview

Regulatory oversight of nuclear power plants is an essential aspect of the application of the technology, albeit not generally considered a specific engineering discipline. Regulation affects reactor design and operation by setting requirements at both a high level (safety goals, system requirements, operations performance metrics, etc.) and in more detail, and through regulatory review of design and operation.

Section 2 looks at overall regulatory requirements. It begins by explaining the need for regulation. It then looks at generic aspects such as regulatory structure and independence, which tend to be broadly similar in advanced nuclear-power-capable countries. It discusses how a good regulator works through drafting standards and guides and through independent review, but emphasizes that the operator is ultimately responsible for safety. It describes licensing milestones (site licence, construction licence, operating licence, decommissioning licence, and licence to abandon), which are common to most countries.

In Section 3, different regulatory approaches are briefly contrasted, varying from risk- or goal-driven at one end to highly prescriptive at the other.

Section 4 gives a number of case studies of regulatory behaviour (in the same spirit as Chapter 13, of learning from real experience)—not to suggest that the regulator was primarily responsible for an event, but that weaknesses in the overall regulatory approach led to inattention on the part of the industry to certain risks.

Section 5 discusses a recent tool for facilitating the licensing of a new design: a pre-project licensing review.

Section 6 gives some international and national examples of organizations which influence or apply regulatory requirements. Specifically, we summarize the consensus developed by the International Atomic Energy Agency (IAEA) as reflected in its guides and touch briefly on regional organizations. Then we discuss examples of prescriptive (United States) and non-prescriptive (United Kingdom) approaches.

Safeguards are described in Section 7. Security is also covered briefly in Section 8.

Sections 9 and 10 cover the Canadian approach. This can be considered as a balanced approach, mixing prescriptive requirements and overall goals. The mandate and organization of the Canadian Nuclear Safety Commission (CNSC) is presented in Section 9. The structure of Canadian Nuclear Regulations and the CNSC's Regulatory Documents and Regulatory Guides is summarized. Certain key Regulatory Documents affecting design and operation are presented in more detail. The licensing process in Canada for both existing and new nuclear power plants is described in Section 10; this includes a summary of the environmental assessment process.

Three supplementary sections follow. Section 11 gives some problems for the student to work through. Section 12 is an Appendix giving some examples of U.K. Safety Assessment Principles as typical of a non-prescriptive approach. Section 13 is an Appendix listing the information that is typically required in Canada when applying for construction and operating licences for nuclear power plants.

Reactor regulation is a very broad field, and we can cover only the essentials in this chapter. Most sections in the text list references to documents or published papers that the interested reader can pursue for more detail: see Section 14 for the list of references. Section 15 concludes the chapter with a glossary of terms.

1.2 Learning Outcomes

The goal of this chapter is for the student to understand generically:

- The need for regulatory oversight of nuclear technology
- How a regulatory agency is structured
- How it fulfills its responsibilities
- The regulatory process and milestones
- The nature of a regulatory review
- Enforcement of regulatory requirements
- Common threads in international approaches to regulation
- Different approaches to regulation (prescriptive, goal-based, mixed)
- Concepts behind safeguards and security.

In addition, the student will gain a familiarity with the organization and mandate of the Canadian regulatory organization (the Canadian Nuclear Safety Commission, or CNSC). The student will understand the Canadian licensing process for both new and existing reactors, as well as acquiring an overall knowledge of CNSC's most important requirements and guides.

2 Generic Regulatory Requirements

This section covers regulatory requirements and processes in general, supported by selected examples. Later sections give details for Canada.

2.1 Why is a Regulator Needed?

Nuclear power is an inherently hazardous and complex technology. Society regulates such technologies, especially if they are relatively new—non-nuclear examples include prescription drugs and air travel. Regulatory oversight of a technology can encompass most or all of the life cycle, including site selection, design, construction, commissioning, operation, decommissioning, and site abandonment. In addition, fuel fabrication and management of spent fuel (should it leave the plant site) are also regulated, although these aspects are not covered in this chapter.

Regulators are authorized by the government—usually the national one—and have strong legal powers to set requirements and to intervene in the technology they regulate, e.g., to order a drug to be withdrawn from the market, or to order a nuclear power plant to make changes. They can use sanctions (fines or prison) on both corporations and individuals in case of egregious non-compliance.

An "ideal" regulatory framework balances the risk of the regulated technology against those of similar technologies, so that social risks are rationalized. This hardly ever happens because the mandate of regulators is usually restricted to a specific technology. Nuclear power tends to be regulated more strictly (i.e., lower risks and more risk aversion) than comparable technologies. There are many reasons for this which we do not have space to explore, but which have been touched on briefly in Chapter 13, and which include voluntary versus involuntary risk, perceived risk versus benefit, association of radiation with atomic weapons and cancer (the "dread" factor), and public unfamiliarity with the technology. The interested reader is referred to the literature on this subject. [Starr1969] and [Slovic1987] are good places to start.

One of the key functions of a regulator is that through the *potential* of independent verification of *any* aspects of a licensee's work, the regulator influences *all* a licensee's internal processes, because any piece of safety-related work can be audited. In particular, the simple *existence* of regulatory oversight stops the licensee from internally accepting deficient safety cases or accepting too readily that their assumptions are right and that they have thought of everything. In other words, oversight encourages the building and maintaining of an adequate safety culture. Regulatory oversight provides a critical independent challenge to a licensee's premises, assumptions, and positions and affects far more than the actual items that a regulator reviews.

2.2 What a Regulator is Not

A good regulator does not remove the onus for safe plant design from the designer or that for safe plant operation from the operator. *This is a key concept.* The ultimate responsibility for safe plant operation lies with the licensed operator. A regulator sets the framework and the rules to be followed, but these do not guarantee a safe plant. A deficient regulatory structure, or a regulator that is not sufficiently independent from government, may contribute to an accident by inadequate oversight, or inadequate requirements, or by being so prescriptive that the operator relinquishes the responsibility to maintain a questioning attitude. However, an operator is not absolved by a weak regulator.

Conversely, a good regulatory structure defines a climate of openness, fairness, and high expectations of safe performance that operators will internalize. In addition, a good regulatory structure ensures that international regulatory trends and approaches are readily adopted and implemented by a national regulator.

In any case, it is impossible for a regulator to check everything. This has two implications:

- there is an implicit understanding that once a licence has been given, the licensee will follow the rules and that the regulator is there to verify selected activities from time to time as it sees fit, usually in some risk-informed manner, as discussed in Section 2.5. This is called "trust but verify"[1]. See Section 2.3.3.
- a regulatory "pass" does not guarantee that the plant is safe, just as a corporate audit does not remove the responsibility of the corporation to exercise fiduciary responsibility, and just as such an audit may miss mistakes.

As stated in [IAEA2000]: "The prime responsibility for safety shall be assigned to the operator. The operator shall have the responsibility for ensuring safety in the siting, design, construction,

1 This is a Russian proverb (Доверяй, но проверяй) originally applied to US-USSR relations during the Cold War.

commissioning, operation, decommissioning, close-out or closure of its facilities, including, as appropriate, rehabilitation of contaminated areas; and for activities in which radioactive materials are used, transported or handled." When an operator takes over a plant, it formally assumes most of the responsibility for design safety. In other words, the "design authority" responsibility is transferred from the technology vendor to the operator. In fact, the operator is required to satisfy itself that the design is adequate *before* assuming operating responsibility. Although technical aspects of the design authority can be delegated in part to the vendor, informed oversight cannot be delegated, and the operator must remain at least an "intelligent customer". In any case, this does not absolve the design organization from its safety responsibilities.

2.3 How a Regulator Exercises its Responsibilities

2.3.1 Scope

Generally, the authority of a regulator is enshrined in national legislation, which gives it the ability to permit (or deny) siting, construction, commissioning, operation, decommissioning, and site abandonment of nuclear facilities, and to control the use of radioactive material. Without a licence for a particular activity, it is illegal to proceed.

Typically regulatory authority covers more than just nuclear power plants (NPPs), including any significant nuclear activity (uranium mining, radioactive sources, research reactors, medical and industrial uses of radiation, radioactive waste disposal, etc.). However, this chapter focusses only on NPPs.

Most nuclear regulators also take on enforcement of national policy on safeguards (Section 7) and on security (Section 8) as applied to nuclear power and represent the national government in international fora on nuclear safety.

2.3.2 Nuclear power plant licensing

The steps in the licensing process, through which a regulator can exercise authority, each involve submission by the applicant of information required by the regulations (Section 10). The required information is discussed in more detail in Section 10.1 for Canada; this section gives an overview.

Typically, there are up to eight major approval milestones for a nuclear power plant. In each, the operator submits the required documentation; the regulator reviews this and (normally) grants a licence to start the milestone activity[2]. The regulator continues to review and monitor progress as the milestone is implemented. Typical milestones are:

- Environmental assessment (including site evaluation)
- Site preparation licence
- Construction licence
- Initial fuel loading
- Low-power commissioning

2 Federal, provincial, and even municipal government bodies may require many other regulatory approvals, which are outside the scope of this chapter.

- Operation
- Decommissioning
- Site abandonment (i.e., return to unrestricted usage).

In addition, most regulators perform on request a preliminary review of an NPP design even before a construction licence application, to reduce the risk of licensing issues arising during the project stage when they are difficult and expensive to address. In Canada, this is called a pre-licensing vendor design review [CNSC2012]. In the United States, it is called design certification [USNRC2012], and in the United Kingdom, generic design assessment [HSE2008]. This topic is discussed in Section 5. Note that there are differences in the depth, scope, and implications of these approaches in different countries.

A regulatory review is usually performed against a set of published standards, requirements, and "expectations" (typically through laws, regulations, and guides). Laws are laws of the land, set by the national government; regulations are requirements set by the government (which in some countries are also laws of the land); and guides are non-mandatory "good practices" issued by the regulatory agency. The licence itself is a legal instrument and typically contains additional specific requirements that must be met. In addition, the regulator may require, or the operator may volunteer, compliance with other national standards. In Canada, these are developed by the Canadian Standards Association (CSA). Every country has its own set of requirements, but now there is more and more international coordination, initially after the severe accidents at Three Mile Island and Chernobyl, and now post-Fukushima[3].

Usually, there is some risk basis for regulatory requirements, which are generally a mix of risk-informed and prescriptive requirements based on past experience, as discussed in the accident case studies in Chapter 13.

In many countries, but not all, regulatory deliberations and decisions are made openly, with many opportunities for public input.

Given the power of the regulator, most regulators set up checks and balances to remain fair. Most regulators are structured somewhat like a corporation, with a Commission at the top supported by a small dedicated group of people, and a large separate specialized technical staff which assesses the safety case in detail and presents its conclusions and recommendations to the Commission. The Commission makes the final decision, not the staff. The Commission reports directly to, or is accountable to, the national government in a way that is independent of the proponent. Some regulators have independent advisory committees (e.g., the United States Nuclear Regulatory Commission (USNRC) has an Advisory Committee on Reactor Safeguards (ACRS) consisting of highly respected technical experts). Such committees are independent of the staff, so that technical inputs to the Commission come from more than one source [USNRC2012a]. This is a "typical" description—there are differences in the organization of regulators in different countries because the regulatory structure is the responsibility of each national government.

National and international peer reviews of regulators use the yardstick of international best practices to encourage improvement, e.g., as implemented by the IAEA through its Integrated

3 Post-Fukushima refers to the changes in nuclear safety regulations and requirements in response to the nuclear accident in the Fukushima Dai-ichi NPP in Japan in March 2011.

Regulatory Review Service (IRRS).

2.3.3 Ongoing oversight

Granting of a licensing milestone is only part of a regulator's scope. Regulators also monitor, through documentation review and site inspections, the construction, commissioning, operation, and decommissioning of nuclear power plants. Trend indicators are used as input to decisions to take regulatory action. In particular, assessment of the safety culture in different parts of the nuclear infrastructure is an important indicator of the overall health of the nuclear safety structure and organization (for a discussion of safety culture, see Chapter 13). An operating licence renewal or major plant changes provide opportunities (or requirements) for the operator to perform an in-depth re-assessment of the plant against modern standards and to close any gaps where it is practical to do so.

Internationally, it is becoming common for periodic safety reviews (PSRs) to be performed, typically every ten years [IAEA2013]. The purposes of these are to:

- assess the cumulative effects of plant aging and plant modifications, operating experience, technical developments, and siting aspects, and
- assess plant design and operation against applicable current safety standards and operating practices.

PSRs are particularly useful if the licence renewal period is long (40 years or more in many countries).

More routinely, regulators perform audits on key aspects throughout the nuclear-facility life cycle, effectively “sampling” performance. Negative audit findings in an area will often trigger broader and more intrusive regulatory audits, until the regulator is satisfied that non-compliances are isolated, or conversely that regulatory action is warranted to ensure that any systemic deficiencies are addressed.

2.3.4 Nuclear emergencies

A regulator has a special role in nuclear emergencies. Although practices vary from country to country, the regulator is *not* expected to take control of a station during an emergency or to direct the operators. However regulatory approval may be needed for such things as planned containment venting. Instead, the regulator is often responsible for, or heavily involved in, emergency (off-site) planning and in coordinating the various governmental bodies involved in public notification, sheltering, prophylactic iodine medication, and evacuation. In some cases, the regulator may be either *de jure* or *de facto* the spokesperson to the public.

2.4 How a Regulatory Review is Done

The following are some of the main tools that a (generic) regulator uses to perform an independent review of a licence application[4] [IAEA2002]. They include:

4 Often the Safety Report is equated with the documentation required for a licensing milestone (called the safety case in some countries), but this is not correct—many more documents are reviewed, as described in Figure 14. The Safety Report as a minimum consists of a detailed design description, a deterministic safety analysis, a summary of the probabilistic safety assessment, a description of programmatic aspects such as quality assurance

- Issuing requirements and guidance for the scope, content, and quality of the safety case. This ensures that the licensee or proponent is aware beforehand of what is required and desired. Typical material includes high-level requirements such as safety goals or dose limits ([HSE2006], [CNSC2008]); lower-level requirements such as the scope of safety analysis [CNSC2008b]; and guidance on acceptable methods [CNSC2012b]. Most jurisdictions also issue requirements on design (e.g., [HSE2006], [CNSC2008], [USNRC2012b] with various levels of prescriptive detail.
- Issuing Review Guides for regulatory staff use so that their reviews are consistent and complete. Some of these are published ([HSE2002], [USNRC2012c], [CNSC2013]), while others remain internal.
- Performing an initial acceptance review of the safety case, for completeness.
- Detailed specialist review of the safety case, using such tools as:
    - Line-by-line review using the Review Guides;
    - Independent calculations using the same computer codes as the licensee, or using independent codes;
    - Expert elicitation, including use of outside panels or individuals and independent analysis by consultants;
    - Assessment against written international standards (e.g., IAEA), industry standards (e.g., those from the Canadian Standards Association (CSA)), or against the licensee's own procedures;
    - Quality assurance review and audit, including management and safety culture;
    - Review of the completeness and appropriateness of the research and development support for any step in NPP implementation, including design, site licensing, etc.;
    - Visits to the site;
    - Consultation with international bodies and fellow regulators;
    - Independent experiments or independent analysis of industry experiments;
    - Questions arising from the above to the licensee and discussion and review of the answers.
    - Extensive technical meetings with the proponent.
- The staff review results are consolidated.
- The position is communicated to the Commission in formal meetings, at which the licensee has the opportunity to present its position. The meetings are public, along with the information that is reviewed and discussed at the meetings. It is the Commission that gives the approval to proceed with the relevant milestone.

2.5 Regulatory Independence and Social Policy

Regulatory bodies generally report to a Minister in Cabinet, or to Parliament through a Minister (as is the case in Canada), or to a similar level of the national government. The reporting is usually independent of the industry at the government level [IAEA2000]. Personnel movement between industry and the regulator is fairly common, especially in smaller countries, and is

and human factors, and demonstrations of compliance with regulatory requirements. See [USNRC, 1978] and [IAEA, 2004] for examples of the format of a Safety Report; the former is far more widely used. Details of the probabilistic safety assessment are usually submitted along with the Safety Report.

beneficial because it ensures that regulatory staff have deep hands-on knowledge of the technology they are to regulate. Often personnel movement occurs internationally, which helps internationalize and harmonize regulatory experience.

At the top level of the regulator, the Commission Chairman, and usually the Commission members, are appointed by the government, and therefore the process is political (in the sense of reflecting the will of the people through their elected representatives). The government provides ultimate oversight of the regulatory body, but rarely formally intervenes in licensing decisions.

Regulatory decisions must balance risks, not eliminate them (risk elimination is an impossibility in almost any technology). Moreover, although most regulators say they evaluate only safety and do not explicitly acknowledge benefits, in fact they have a responsibility to account for the fact that an activity may have significant net social benefit. In this sense, regulation sets (or reflects) social policy. Hence, regulatory approval means that the project poses an *acceptable* level of risk. Very few regulators use *only* risk as a regulatory tool (i.e., based just on the probabilistic safety analysis (PSA)); see Chapter 13 for a discussion on PSA. Many regulators use or accept a risk framework to sharpen decisions—this is called *risk-informed decision making* (RIDM) and is a combination of PSA insights and traditional deterministic requirements. This is a broad topic—for more detail, see [Apostolakis2004], [Bujor2010], [CSA1997], and [USNRC2002]. In certain cases, usually when a retrofit is being considered, a cost-benefit case prepared by the proponent may be considered to ensure that the cost is not disproportionate to the benefit; see [HSE2001], [CNSC2000].

Finally, regulators must have adequate resources and experience, but they do not have to replicate all the resources of the designer or operator; cf. our example of a financial audit. To ensure adequate financial resources, regulators are given strong government support at the early stage of their development, whereas later most of their daily operations are on a cost-recovery basis from the licensees.

The above description applies to countries with an established nuclear industry. A country just embarking on a nuclear program, but with no nuclear infrastructure, faces special challenges in developing appropriate expertise and organizations ([IAEA2012b], [Popov2012]).

Four mechanisms have been used. These are not exclusive and are often used in combination.

1. The typical mechanism in the past has been to start with a research reactor and to use it to develop staff for design, operating, and regulatory functions from that base. This route was followed by Canada, where the power reactor program benefited from staff trained in the research reactors (NRU, NRX) at Chalk River. Indeed, the Atomic Energy Control Board (AECB), established in 1946 under the Atomic Energy Control Act, had responsibility for making regulations *and* for the Chalk River research project until Atomic Energy of Canada Limited (AECL) was created in 1952 under the AECB. Two years later, the Canadian Government formalized the separation of the designer/operator of the Chalk River site from the regulatory agency [Sims1980].
2. A second mechanism has been to use the vendor of a power reactor to help create the required infrastructure in the country purchasing the reactor by technology transfer and training of operating personnel. The regulatory staff in the purchasing country are developed under an agreement with the regulator of the vendor's host country. This can go as far as "importing" experienced regulatory staff.

3. A third mechanism is to use IAEA documents and assistance. This organization has developed a comprehensive set of requirements and guides covering all aspects of commercial nuclear applications, including the organization and management thereof. The IAEA also gives assistance to countries developing a nuclear program, such as training courses in nuclear regulation [IAEA2002c].
4. A fourth mechanism is to hire *technical support organizations* (TSOs) to provide technical assistance to the developing regulatory body. These are neutral official organizations which are either part of the regulatory body or are separate, for example a national laboratory. See [IAEA2010] for recent developments.

Figure 1 from [IAEA2011] gives an idea of the steps and timescale involved in a new national nuclear power program.

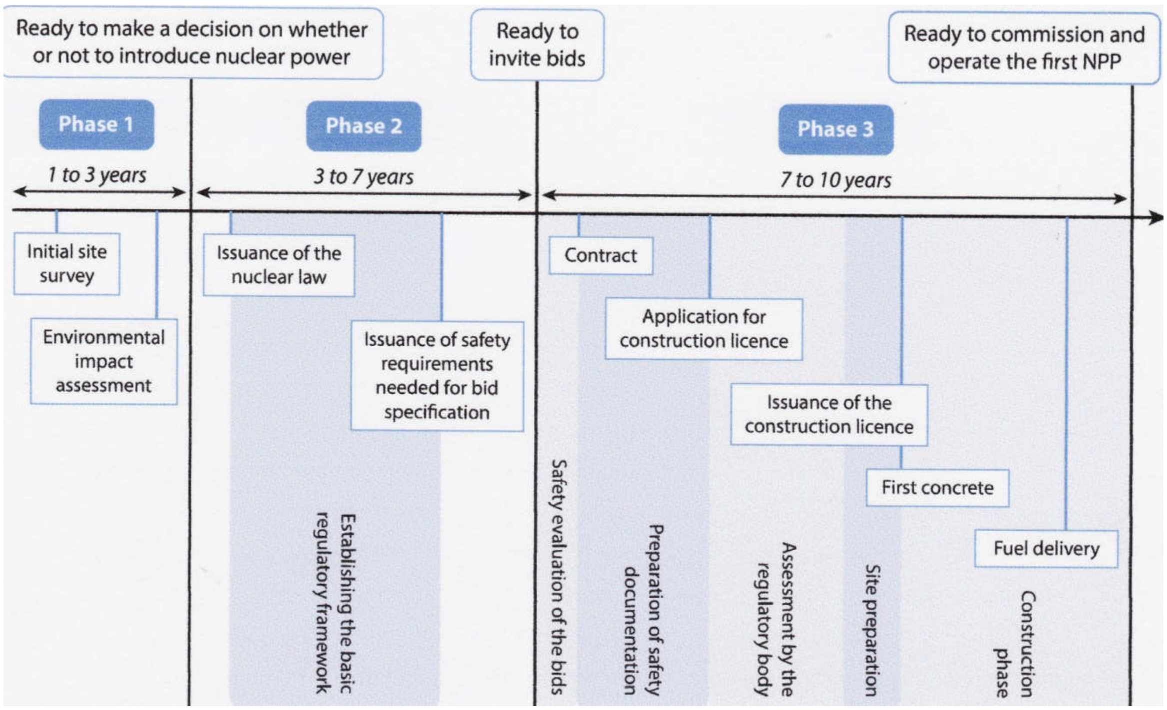

Figure 1 Steps in the development of a nuclear power program

3 Regulatory Approaches

The approaches taken by regulatory agencies across the world tend to fall into four general categories (based on the proven approach used by the regulator in the past; of course, this assertion is oversimplified, and many regulators allow alternative approaches that can be a mix of the four listed below):

1. A largely risk-based approach (e.g., the early U.K. Farmer curve [Farmer1967], and Argentina [Barón1998])
2. A risk-informed, largely non-prescriptive approach with specification of goals or results, not the process (early Canada, some early IAEA, current U.K.);
3. A risk-informed, but more prescriptive approach (current Canada, IAEA);
4. A highly prescriptive approach, with specified detailed requirements (e.g., USNRC and the U.S. Code of Federal Regulations).

Each approach has its advantages and disadvantages.

A risk-based approach is logical, quantifies and balances risk, and leaves major design and operating decisions up to the proponent, who decides how to meet the risk goals. It thereby accommodates and even fosters innovation and evolution. On the other hand, it can lead to uncertainty in licensing because demonstration of numerical risk can be subjective or limited by lack of knowledge. It may not account sufficiently for previously unknown failures, which might be addressed more effectively by a more prescriptive defence-in-depth approach. In particular, cross-linked or common-cause failures (see Chapter 13) are difficult to identify *completely* in a PSA, so that the contribution to risk from these causes can be underestimated.

A mixed approach, which uses both risk-based and prescriptive approaches to various degrees, captures most of the benefits (and some of the disadvantages) of both extremes and generally has served Canada and the United Kingdom well. In particular, it is effective in providing defence against accidents not previously identified, without too much misallocation of resources to truly rare low-risk events.

A highly prescriptive approach in principle leads to well-defined licensing rules and more regulatory certainty and tends to produce an apparently conservative design. However, it can shift the burden of proof of safety from the designer/operator to the regulator. If the designer/operator is required mainly to follow detailed rules set by the regulator, and if the regulator misses something, part of the responsibility for safety has shifted subtly from the proponent to the regulator. Furthermore, de-emphasis of risk leads to some resource misallocation to severe but rare events, as opposed to more frequent ones with *apparently* milder consequences. We shall cover a case study of this situation (Three Mile Island) in the next section.

Much of the world, especially those countries using designs originating from U.S. light-water reactor (LWR) technology, follows the U.S. regulatory approach, largely because the regulatory approach was adopted along with the LWR technology.

4 Case Studies

This section considers a few case studies of regulatory behaviour. Where possible, the regulatory agency's self-evaluation (or that of an independent body) is used, rather than the authors' opinions. The case studies are presented not as a criticism of a particular organization, but as lessons learned about effective regulatory behaviour, as was done for design and operational safety in the case studies in Chapter 13. Some of these examples are also covered in Chapter 13, but with an emphasis on design and operation, rather than regulation.

Success is marked by the *lack* of accidents and "near misses", and just as an accident cannot be laid solely at the feet of a regulator, neither can the lack of accidents be solely ascribed to the quality of regulation. As Three Mile Island, Chernobyl and Fukushima were studied from the technical point of view in Chapter 13, we shall now look at these accidents from the regulatory point of view.

4.1 Three Mile Island

The TMI sequence of events was covered in Chapter 13. A minor event escalated through a small and unrecognized loss of coolant into a partial core melt which was contained in the vessel. Two commissions were struck to carry out an independent review.

The President of the United States appointed a Commission headed by John G. Kemeny. Their report [Kemeny1979] was very broad. Their concentration was on human aspects: "The equipment was sufficiently good that, except for human failures, the major accident at Three Mile Island would have been a minor incident." Of interest here are their findings on the U.S. regulatory structure at the time, which are summarized as follows:

- The regulations were too voluminous and complex, required immense effort for compliance, and equated compliance with safety;
- The preoccupation with the most severe accident (the largest-break LOCA) took attention away from more likely, but slower-developing accidents, which were therefore not analyzed in depth;
- There was too much preoccupation with equipment performance rather than human performance;
- There was no requirement to look beyond the single events specified by the USNRC, for example to multiple failures;
- The role of systems classified as "non-safety-related" in causing accidents was not recognized;
- There was no systematic way of evaluating prior operating experience or looking for patterns;
- There were serious deficiencies in internal communication in the USNRC.

An additional review by the Nuclear Regulatory Commission Special Inquiry Group [Rogovin1980] covered very similar ground, albeit with more comments on the USNRC internal decision-making processes.

Subsequent to TMI, and based on the findings of the Kemeny Commission, severe accidents, emergency preparedness, plant performance monitoring, and human factors were given far more prominence on the regulatory side. Insights from PSA were used more widely, not only to reveal severe accident vulnerabilities, but also to flag requirements that attracted inordinate resources compared to the risk they mitigated. The industry formed cooperative groups such as the Institute of Nuclear Power Operations (INPO) to promote high standards of safety and reliability through plant evaluations, training and accreditation, events analysis, and information exchange and assistance.

4.2 Fukushima

The Fukushima Dai-ichi sequence of events was covered in Chapter 13. A beyond-design-basis tsunami caused a loss of all electrical power in four units, resulting in severe core damage or melting and possible containment failure in the three reactors that contained fuel.

With respect to the Japanese regulator (the Nuclear and Industrial Safety Agency (NISA)), the National Diet of Japan Nuclear Accident Independent Investigation Commission [Japan2012] concluded that "root causes were the organizational and regulatory systems that supported faulty rationales for decisions and actions", and in particular that the inadequacy of the design basis for Fukushima was known to both the utility and the regulator, but was not acted on. The regulator lacked separation from the utility. The Commission recommended formation of a new regulatory body which would be independent, transparent, professional, consolidated, and proactive.

The Japanese Government also established the "Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company", an independent committee largely composed of academics. Their final report [Japan2012a], although more technical than the Diet report, raised the same issues and called for reorganization of the regulatory body. They also noted NISA's attention to short-term rather than long-term issues. In addition they focussed on NISA's performance after the event, in emergency measures off-site, and in public communication.

As of this writing (early 2014), the Japanese regulatory body has been reorganized and renamed the Nuclear Regulation Authority (NRA).

Regulators worldwide have applied the technical lessons learned, as outlined in Chapter 13. In terms of national response, in particular, the radiation threshold levels that were used for evacuation were based on the Linear No Threshold (LNT) hypothesis, which implies an unrealistically high level of risk for individual doses of radiation <100 mSv, although no effects on human populations have actually been observed at that level. Although there were no deaths due to radiation from the accident (and there are not expected to be), the evacuation itself resulted in many unnecessary deaths [Tanigawa2012].

4.3 Chernobyl

The Chernobyl sequence of events was covered in Chapter 13. A test which involved running down the main reactor coolant system (RCS) pumps while at low power ended up in a power transient due partly to the voiding of the core, but mainly to the *reverse* action of the shutdown system, destroying the reactor core and bypassing the containment.

The International Safety Advisory Group (INSAG), which provides independent advice to the IAEA Director-General, performed very extensive fuellings of the Chernobyl accident [IAEA1992]. This reference includes as an Appendix the *Report by a Commission to the USSR State Committee for the Supervision of Safety in Industry and Nuclear Power*, which covered the technical facts and the role of the regulatory structure. It noted that:

- There were known violations of the safety standards and regulations in force at the time in the design of Chernobyl Unit 4, but the design was approved and authorization given for construction by all the relevant authorities and regulatory bodies.[5]
- This deficiency resulted from a lack of a well-organized group of experts endowed with its own resources, rights, and responsibilities for its decisions;
- The USSR State Committee for the Supervision of Nuclear Power Safety could not be regarded as an independent body because it was part of the same state authority responsible for the construction of nuclear power plants and for electricity generation.
- The regulatory bodies had no legal basis, no economic methods of control, and no human and financial resources.
- The operating organization did not have ultimate responsibility and decision-making authority for safety.

5 Note added by authors: there are always outstanding regulatory issues when a plant is given a licence—what is important is that the process to determine which issues are acceptable should be an open and robust one.

4.4 Olkiluoto

It is not just accidents than can reveal a regulatory problem. Cost and schedule overruns because of poor communication between the vendor/operator and the regulator can be very damaging to a nuclear build project. This has been exemplified by the construction of the third nuclear power plant unit at Olkiluoto in Finland. The reactor is based on the European pressurized-water reactor (EPR) and is the first of its kind to have started construction. It was meant to start operation in 2009, but as of this writing (early 2014), it is projected to come into service in 2016. This delay has been accompanied by a cost overrun of almost double the turnkey price of ~3.5 billion euros.

Because the matter is currently in legal dispute, the parties have not published much objective analysis of what went wrong. However, the Finnish regulator (STUK) did comment publicly on several occasions, listing lessons learned as follows, from [STUK2006], [Laaksonen2008], [Laaksonen2009], [Tiippana2010], [IAEA2012]:

- "too ambitious original schedule for a plant that is first of its kind and larger than any NPP built earlier;
- inadequate completion of design and engineering work prior to start of construction;
- shortage of experienced designers;
- lack of experience of parties in managing a large construction project;
- world-wide shortage of qualified equipment manufacturers".

The operator TVO, and particularly the vendor AREVA, have offered their own perspective, in which one of the causes mentioned is evolution of Finnish regulations during the construction process, which introduced additional uncertainty into the licensing process.

Of particular interest to the thrust of this chapter is the need for mutual understanding between the regulator and the operator on how the regulatory practices are to be applied:

"The licensee and the regulator need to discuss early enough on how the national safety requirements should be best presented in the call for bids.

- just making reference to national requirements and regulatory guides is not adequate to ensure that requirements are correctly understood by vendors".

With respect to the last point: In Finland, before a project is committed, the Government makes a "Decision in Principle", for part of which the regulator reviews the basic design requirements and main safety features of each proposed alternative design and gives a formal preliminary safety assessment. STUK confirmed in this assessment that "no safety issues can be foreseen that would prevent the proposed plant(s) from meeting Finnish nuclear safety regulations". Although the regulator can apply caveats to this statement in terms of changes that would be required, it is not based on a very detailed review.

5 Pre-Project Licensing Review

The risk to a project from delays associated with uncertainties in the regulatory legal process and requirements has been recognized for decades, spurred by cost and schedule overruns in nuclear plant construction in the United States in the 1970s. The solution adopted in many countries has been a form of pre-project licensing review which is done before project commitment. Typically, a vendor or utility requests a review of a proposed design against the regulatory requirements of the country in which it is to operate. Such a review ensures that the vendor understands the regulatory requirements and enables regulatory questions to be flushed out and answered earlier. The review is very thorough and is similar in many ways to the construction licence review, but focussing mainly on design details rather than operation. The format of such a review, and the extent to which it is binding on the regulator, depend on national legal and cultural practices. We describe briefly three examples.

In Canada, a designer can request a Pre-Licensing Vendor Design Review, which [CNSC2012]

> "…is to inform the vendor of the overall acceptability of the reactor design…

A Pre-Licensing Vendor Design Review evaluates whether:

- the vendor understands Canadian regulatory requirements and expectations;
- the design complies with, as applicable, CNSC regulatory documents RD-337[6], Design of New Nuclear Power Plants or RD-367, Design of Small Reactor Facilities, and related regulatory documents and national standards;
- a resolution plan exists for any design issues identified in the review".

The review is not binding on the CNSC (i.e., the CNSC can request repeated in-depth reviews on the same topics during construction licence review, and CNSC review results may be subject to change from pre-licensing to the construction licence review).

In the United States, Standard Design Certification is a legal process covered by Part 52 to Title 10 of the Code of Federal Regulations [USNRC2012]. The design submitted and the review are both comprehensive, although some detailed design normally performed in the project phase may be more conceptual (e.g., details of control and instrumentation design). When completed, the product is a standard reactor design certified by the Commission, independent of a specific site, through a rulemaking action (Subpart B of Part 52). This rulemaking action can certify portions of a reactor design for 15 years.

Separately, a licensee can apply for an *early site permit* for approval of a site for one or more nuclear power facilities. This is also separate from the filing of an application for a construction permit or a *combined licence* (see below) for the facility. A specific design is not required for an early site permit, but the design eventually chosen must fit within the safety and environmental parameter envelope requested and specified in the early site permit.

As a third option, a licensee can request a combined licence, which is a combined construction permit and operating licence for a nuclear power facility.

A licensee can use any combination of these tools. For example, a licensee can obtain an early site permit based on the environmental and safety performance envelope of a set of designs; can obtain certification of a specific design that meets the envelope; and can then ask for a combined construction and operating licence for the certified design on the approved site. Standard design certification and early site permits are legally binding, subject to conditions (specified during the certification process) to be met by the detailed project design.

In the United Kingdom, the Office for Nuclear Regulation (ONR) and the Environment Agency

6 Note that the CNSC document titles are in the process of changing; this document has been renamed and revised as REGDOC 2.5.2. Other CNSC regulatory documents are being revised and renamed as REGDOCs.

(EA) offer a *generic design assessment* (GDA) of new reactors. The purpose is [HSE2008] an "assessment of the safety case for a generic design, leading to issue of a design acceptance confirmation if the outcome is positive". It consists of four phases: the first is preparation of the safety case by the proponent, and the next three are reviews by ONR and EA at increasing levels of detail, namely: 1) fundamental safety overview; 2) overall design safety review; and 3) detailed design assessment. A design acceptance confirmation is then issued, subject to possible conditions and exceptions, if the design is considered acceptable. Once completed, a GDA ensures that within the scope of the design, ONR review results are binding. ONR may extend the review during the construction licence review, but the results of the prior GDA remain binding.

6 International and National Examples

6.1 International Organizations

A number of international bodies have a quasi-regulatory role. Regulation is still a *national* legal responsibility, and therefore these organizations do not have formal authority. However, they influence governments, national bodies, and nuclear organizations, and if a country formally adopts their guidance, it takes on the force of national law or regulation.

As before, we give an overview, and the reader may find out more in the references.

6.1.1 IAEA

The origins and purposes of the International Atomic Energy Agency (IAEA) are described in Chapter 13, to which the reader is referred.

Its current document structure with respect to nuclear safety and regulation includes a hierarchy of Principles, Standards, and Guides, as shown in Figure 2, from [IAEA2012a]. Although these have no legal or regulatory force unless they are formally adopted on a national level, they are seen as setting minimum international requirements for safety and regulation. The structure and nomenclature in Figure 2 are self-explanatory, with Safety Fundamentals and Safety Requirements being mandatory (if adopted) and Safety Guides being recommendations and guidance on how to comply with the Requirements. As of this writing (early 2014), they have been formally adopted in countries such as China and the Netherlands; are used directly to establish national requirements in Canada, the Czech Republic, Germany, India, Korea, and the Russian Federation; are used as a reference for review of national standards by most nations; and are also used as inputs by international organizations such as the Western European Nuclear Regulators' Association (WENRA) (Section 6.1.2).

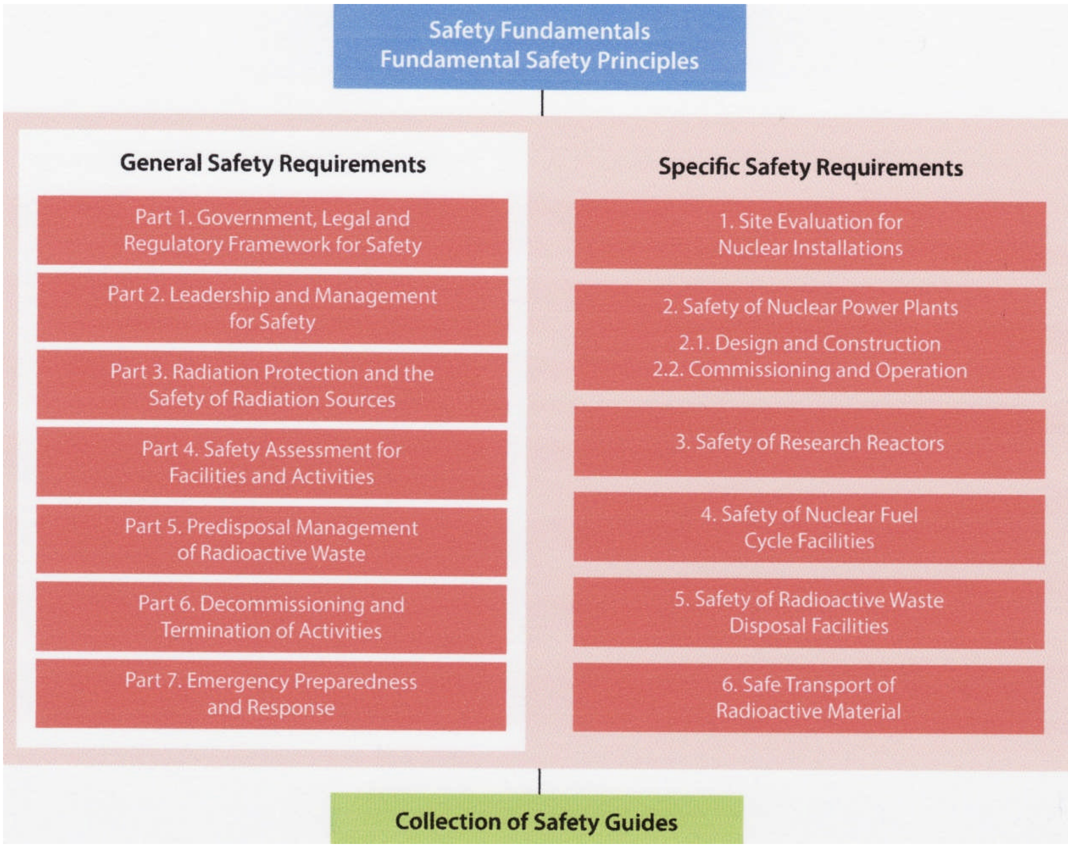

Figure 2 Hierarchy of IAEA safety documents

Of particular relevance to this Chapter, IAEA report GS-R-1 [IAEA2000] deals, among other things, with overall regulatory structure and organization. It is supported by a number of more detailed guides.

Table 1 IAEA guides related to regulation

Report Number	Title
SSG-16	Establishing the Safety Infrastructure for a Nuclear Power Programme (2012)
GS-G-1.1	Organization and Staffing of the Regulatory Body for Nuclear Facilities (2002)
GS-G-1.2	Review and Assessment of Nuclear Facilities by the Regulatory Body (2002)
GS-G-1.3	Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory
GS-G-1.4	Documentation for Use in Regulating Nuclear Facilities (2002)
GS-G-1.5	Regulatory Control of Radiation Sources (2004)
GS-G-3.5	The Management System for Nuclear Installations (2009)
SSG-12	Licensing Process for Nuclear Installations (2010)
SSG-16	Establishing the Safety Infrastructure for a Nuclear Power Programme
GS-G-4.1	Format and Content of the Safety Analysis Report for Nuclear Power Plants (2004)

Some of the key principles reflected in these Requirements and Guides are:

- a regulator's purpose is the verification and assessment of safety in compliance with regulatory requirements;
- it has sufficient resources to perform its job;
- it is effectively independent from other organizations that could influence its decisions;
- it has qualified and competent staff;
- its management system is aligned with its safety goals;
- it may solicit expert advice, but does not delegate decisions;
- it communicates professionally with interested parties and with the public;
- regulatory control is stable and consistent;
- it authorizes all facilities unless specifically exempt;
- authorization is supported by a demonstration of safety submitted by the applicant;
- regulatory review occurs before authorization and over the facility lifetime;
- review is commensurate with risks;
- it inspects facilities;
- it has legal enforcement powers and can require corrective action;
- it issues, reviews, and promotes regulations and guides;
- it maintains records;
- it promotes a safety culture (see Chapter 13);
- it ensures that emergency preparedness arrangements and emergency plans are in place.

Finally, there is a growing international consensus on high-level numerical safety goals. Safety goals are defined and discussed in Chapter 13 (Section 4), and the reader is referred there for details. Almost all regulators who specify safety goals do so implicitly or explicitly on the following basis: the goals are set so that the predicted health effects of normal operation and accidents in nuclear power plants are small compared to other social risks. Although IAEA itself has not specified numerical safety goals, its senior advisory body (INSAG, in [IAEA1999]) has proposed the following targets:

- For existing nuclear power plants:
  - Frequency of occurrence of severe core damage < 10^{-4} events per plant operating year;
  - Probability of large off-site releases requiring short term off-site response < 10^{-5} events per plant operating year.
- For future nuclear power plants:
  - Frequency of occurrence of severe core damage < 10^{-5} events per plant operating year;
  - Practical elimination[7] of accident sequences that could lead to large early radioactive releases.

These targets have been used by many other international and national bodies.

7 i.e., if it is physically impossible for the conditions to occur or if the conditions can be considered with a high degree of confidence to be extremely unlikely to arise [IAEA, 2004a]

Note also that the frequency of the design basis earthquake (DBE) has recently been changed in most jurisdictions from 10^{-3} / year to 10^{-4} / year, meaning that the DBE that new plants are required to withstand is significantly more severe.

6.1.2 MDEP and WENRA

There has been an impetus for several years to "harmonize" nuclear regulations, much as aircraft regulations are common internationally. The ideal is that a reactor design licensed in one competent jurisdiction would be licensable anywhere because the requirements would be the same. In practice, licensing requirements are closely linked to design type, and therefore harmonization has made slow progress because of the wide variety of reactor types requiring different regulations at the detail level.

An initiative called the "Multinational Design Evaluation Programme" (MDEP) was established in 2006 to:

- enhance multilateral co-operation within existing regulatory frameworks;
- encourage multinational convergence of codes, standards, and safety goals;
- facilitate the licensing of new reactors.

It currently includes nuclear regulatory authorities from 13 countries. Its work includes co-operation on safety reviews of specific reactor designs. National regulators retain sovereign authority for all licensing and regulatory decisions.

The Western European Nuclear Regulators' Association (WENRA) was formed in 1999 to develop a common approach to nuclear safety and to be able to review nuclear safety independently in countries applying for membership in the European Union (EU).

One of their earliest reports [WENRA2000] surveyed the state of nuclear safety and regulation in countries applying for EU membership. The report covers the status of the regulatory regime and regulatory body and of nuclear power plant safety. For the former, issues such as independence of the regulatory body, resources, and expertise were priority topics.

Because the predominant type of reactor in Western Europe is the LWR, it is somewhat easier to propose harmonized requirements. WENRA has adopted common top-level requirements for any reactor to be built in Western Europe [WENRA2010]. These are largely consistent with the IAEA Safety Fundamentals [IAEA2006a]. More detailed requirements are given in the WENRA "Reference Levels" publications, e.g., [WENRA2007], for reactor safety.

Finally, as requested by the European Union (EU) after the accident at Fukushima Dai-ichi in March 2011, WENRA proposed [WENRA2011] that a series of analytical "stress tests" be done on all EU nuclear power plants to show their robustness against extreme natural events. Unlike the traditional approach of analyzing design basis accidents (DBAs) and beyond design basis accidents (BDBAs) (see Chapter 13), WENRA proposed an analysis assuming:

> "sequential loss of the lines of defence in a deterministic approach, irrespective of the probability of this loss. In addition, measures to manage these situations will be supposed to be progressively defeated."

In other words, design and accident management measures were to be assumed to fail one after the other and the consequences at each step tabulated to understand the plant's robustness. The initiating events conceivable at the plant site included earthquake, flooding and other extreme natural events. The consequential loss of safety functions included loss of electrical power, including station black-out, loss of the ultimate heat sink, and a combination of both. Each EU country (or country applying for EU membership) completed these stress tests for its own plants and reported the results back to the European Nuclear Safety Regulators' Group (ENSREG), an independent expert body formed by the European Commission, for evaluation.

6.2 National Regulatory Organizations

Although each country operating a nuclear power plant has a national regulatory agency, the overall approach taken generally follows that used in the countries which have designed and deployed the major types of reactors: Canada for pressurized heavy-water reactors (PHWRs), the United States for LWRs, and the United Kingdom for gas-cooled reactors. In this section, we give a brief description of the regulatory approach in the latter two examples; Canada is covered later and in more detail in Sections 9 and 10.

It is impossible in one section of one chapter to cover the full breadth of regulatory philosophy and practices in several jurisdictions. Rather, we focus on the overall philosophy rather than the mechanics of licensing and give references so that the interested reader can find more detail.

6.2.1 USNRC

6.2.1.1 Background

In the United States, the Atomic Energy Act of 1946 established the Atomic Energy Commission (AEC), transferring atomic energy from military to civilian control (see [Buck1983] for a history). Its early years were devoted to nuclear weapons production and research, including the military submarine program, whose reactors became the inspiration for the U.S. PWR commercial power reactor design. The revised Atomic Energy Act of 1954 gave the Atomic Energy Commission the responsibility for regulating and licensing commercial atomic activities. Research, military use, regulation, licensing, and development of the nuclear power industry were all under the same organization, and although it set up separate divisions, the conflicts of interest became more and more apparent, until in 1974 the regulatory functions were transferred to the newly-formed U.S. Nuclear Regulatory Commission (USNRC), which began operations on January 19, 1975.

6.2.1.2 Organization

The USNRC has had enormous influence on regulatory practice in the world because the wide-spread use of LWR technology was accompanied by the LWR regulatory philosophy. Indeed, because almost all the reactors licensed in the United States have been PWRs or BWRs[8,] the regulatory requirements tend to be specific to these designs.

The USNRC is headed by a five-member Commission appointed by the U.S. President for staggered five-year terms. The President designates one member to serve as Chairman. The Commission formulates policies and regulations governing nuclear reactor and materials safety, issues orders to licensees, and adjudicates legal matters brought before it. The Executive

8 The United States have also licensed a fast-breeder power reactor (Fermi 1) and high-temperature gas-cooled reactors (Peach Bottom and Fort St. Vrain).

Director for Operations (EDO) carries out the policies and decisions of the Commission and directs the activities of the program offices.

The Commission is supported by a large technical staff, as well as powerful advisory committees who can challenge both the proponent and the staff, e.g., the Advisory Committee on Reactor Safeguards, or ACRS. Typically, the ACRS consists of well-known and respected scientists and experts, often world-renowned professors drawn from universities. It has its own independent support staff. There is no current equivalent in Canada, although at one point the Reactor Safety Advisory Committee (RSAC), which later became the Advisory Committee on Nuclear Safety (ACNS), had a similar role with the then-AECB, albeit on a smaller scale.

The actual trial-level adjudicatory body of the USNRC is the Atomic Safety and Licensing Board Panel (ASLB). The Panel is composed of administrative judges who are lawyers, engineers, and scientists, and administrative law judges who are lawyers. It is chaired by the Chief Administrative Judge. The Panel conducts all licensing and other hearings as directed by the Commission, primarily through individual Atomic Safety and Licensing Boards or single presiding officers appointed by either the Commission or the Chief Administrative Judge. Individual licensing boards conduct public hearings on contested issues that arise in the course of licensing and enforcement proceedings and uncontested hearings on construction of nuclear facilities.

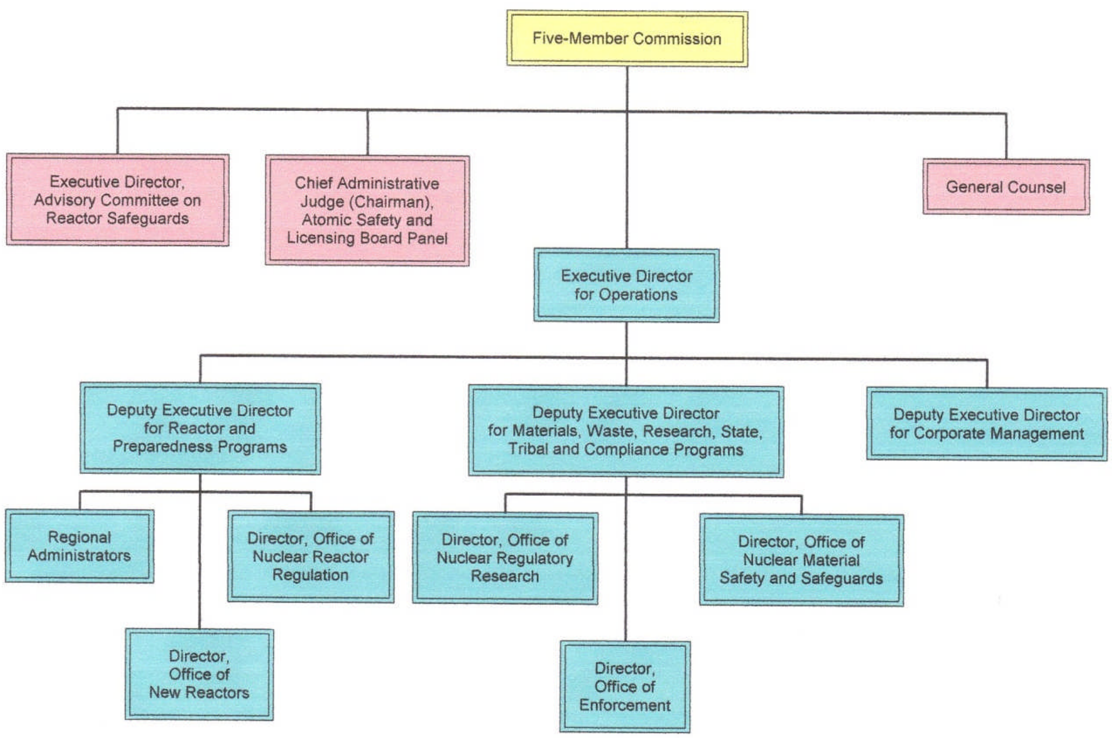

Figure 3 Simplified organization chart of the USNRC

Figure 3 shows a highly simplified organization chart of the USNRC. The five-member Commission (yellow) is supported by the ACRS, the ASLB, and legal counsel, shown in red. The large technical staff (turquoise) is headed by the Executive Director for Operations. For nuclear regulatory purposes, the United States is divided into four regions; the four regional offices conduct inspection, enforcement, and emergency response programs for licensees within their borders. USNRC also has a large and powerful R&D Division which conducts experimental and analytical work of very broad scope, along with development of their own computer tools, independently of utilities and design organizations.

6.2.1.3 Regulatory approach and documents

As we saw with the IAEA and shall see with other regulators, regulatory documents form a hierarchy, with legislation at the top, government regulations and licences next (both of which are enforceable by law), mandatory regulatory requirements set by the regulator next, then optional regulatory guides provided by the regulator, and finally guidance to regulatory staff themselves on how to review a submission. Figure 4 shows such a generic structure.

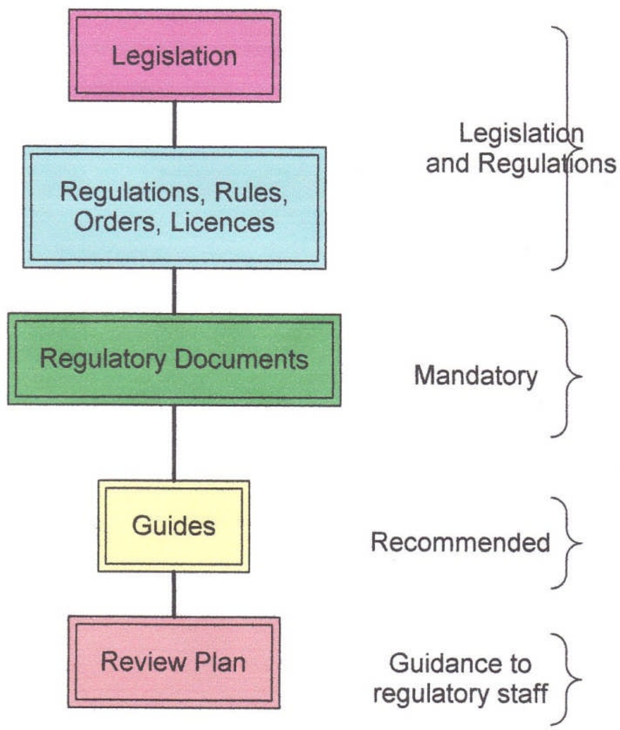

Figure 4 Generic hierarchy of regulatory documents

6.2.1.3.1 Consolidated legislation

In the United States, nuclear energy-related activities are governed by the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended (which created the USNRC). The interested reader is referred to [USNRC2011] as updated, which consolidates all nuclear-related legislation and executive orders and runs well over 1000 pages.

The Nuclear Safety and Control Act in Canada [GovCan2013], by contrast, has 54 pages. [Ahearne1988] is an excellent source of information on the origins of the U.S. regulatory approach and its differences from that used in Canada. Although the work is dated, it is recommended reading to gain an understanding of the differences. One interesting difference in practice is the length of a plant licence; typically, in the United States, it is up to 40 years, whereas in Canada the utility must reapply about every five years.

6.2.1.3.2 Code of Federal Regulations

The technical requirements are covered in the Code of Federal Regulations Title 10 (10CFR), which corresponds to the second box from the top in Figure 4. The requirements are binding on all persons and organizations who receive a licence from the NRC to use nuclear materials or to operate nuclear facilities. Of particular interest are 10CFR Part 50 [USNRC2012d] and 10CFR Part 52 [USNRC2012].

10CFR Part 50 covers requirements for the traditional domestic licensing of production and nuclear power facilities. Much of the main text is legal and procedural, and these aspects will not be discussed further here. Even a detailed technical discussion of 10CFR Part 50 is well beyond the scope of this chapter. We select a few examples to give an idea of the approach.

Section 50.46 states acceptance criteria for emergency core cooling systems for light-water nuclear power reactors. The requirements are in the form of numerical analysis values rather than safety objectives. For example, it is an overall requirement in water reactors to prevent excessive oxidation of the sheath because if it becomes brittle, it can fragment on rewet, and the debris can block fuel cooling. Moreover, at high temperatures, the Zircaloy-water reaction becomes autocatalytic, so that temperature prediction is difficult. Finally the reaction produces hydrogen, which is a source of energy to containment if it burns. In Canada, these requirements are stated as objectives, and it is up to the proponent to justify how they are met. However, in 10CFR Part 50, the acceptance criteria can be quite explicit (from 50.46):

> "(b)(1) Peak cladding temperature. The calculated maximum fuel element cladding temperature shall not exceed 2200° F.
> (2) Maximum cladding oxidation. The calculated total oxidation of the cladding shall nowhere exceed 0.17 times the total cladding thickness before oxidation. As used in this subparagraph, total oxidation means the total thickness of cladding metal that would be locally converted to oxide if all the oxygen absorbed by and reacted with the cladding locally were converted to stoichiometric zirconium dioxide. If cladding rupture is calculated to occur, the inside surfaces of the cladding shall be included in the oxidation, beginning at the calculated time of rupture. Cladding thickness before oxidation means the radial distance from inside to outside the cladding, after any calculated rupture or swelling has occurred, but before significant oxidation. Where the calculated conditions of transient pressure and temperature lead to a prediction of cladding swelling, with or without cladding rupture, the unoxidized cladding thickness shall be defined as the cladding cross-sectional area, taken at a horizontal plane at the elevation of the rupture, if it occurs, or at the elevation of the highest cladding temperature if no rupture is calculated to occur, divided by the average circumference at that elevation. For ruptured cladding, the circumference does not include the rupture opening.
> (3) Maximum hydrogen generation. The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam shall not exceed 0.01 times the hypothetical amount that would be generated if all of the metal in the cladding cylinders surrounding the fuel, excluding the cladding surrounding the plenum volume, were to react."

Although this example illustrates a difference in regulatory philosophy (and not all criteria are this detailed), it is also related to design differences. In PWRs, if the metal-water reaction becomes autocatalytic, there is no nearby heat sink to mitigate it, and it can quickly affect a large part of the core. In CANDU (as discussed in Chapter 13) the nearby moderator can remove heat from the fuel through the pressure tube and has the effect of tempering the metal-water reaction rate.

As another example, consider Appendix A to 10CFR 50, the General Design Criteria [USNRC2012b]. This Appendix consists of 64 basic requirements which underpin much of the technical approach to safety in the United States. Compliance is mandatory. Although high-level, many are focussed on LWRs, as stated in the introduction:

> "These General Design Criteria establish minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission. The General Design Criteria are also considered to be generally applicable to other types of nuclear power units and are intended to provide guidance in establishing the principal design criteria for such other units."

Many of the GDCs *are* generic; for example

> *"Criterion 16—Containment Design*. Reactor containment and associated systems shall be provided to establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment and to assure that the containment design conditions important to safety are not exceeded for as long as postulated accident conditions require."

Some are clearly specific to LWRs, for example:

> *"Criterion 11—Reactor Inherent Protection*. The reactor core and associated coolant systems shall be designed so that in the power operating range the net effect of the prompt inherent nuclear feedback characteristics tends to compensate for a rapid increase in reactivity."

The underlying purpose of Criterion 11 is that a fast reactivity excursion in an LWR, caused for example by a rod ejection, must be compensated for (not necessarily terminated, as discussed in Chapter 13) by negative (Doppler) feedback since (because of the short prompt neutron lifetime) engineered shutdown systems may not be able to act quickly enough (see Chapter 13). It is often misinterpreted as a blanket requirement for a negative void reactivity.

At the same level in Figure 4 are plant licences, rules (U.S. term for regulations), and orders.

6.2.1.3.3 Commission Policy Statements

Commission Policy Statements are an example of Regulatory Documents (third box down in Figure 4). For example, in 2011, the Commission issued a Policy Statement on Safety Culture, setting forth its expectations for industry to promote a positive safety culture. Such notices are published in the U.S. Federal Register.

Given the detail in 10CFR, USNRC staff have less need to issue *mandatory* regulatory documents.

6.2.1.3.4 Regulatory guides

Regulatory guides (fourth box from the top in Figure 4) provide guidance to proponents on implementing USNRC regulations, on techniques used by NRC staff in evaluating specific problems or postulated accidents, and on data needed by staff in its review of applications for permits or licences. Although nominally optional, exceptions taken to regulatory guides in the United States (and most other countries) require thorough justification and significant extra regulatory review.

6.2.1.3.5 Standard review plan

Many regulators now have a standard review plan (SRP, bottom box in Figure 4) written by the regulator and aimed at regulatory staff performing reviews of proponent applications. This approach was first developed in the United States and is now being adopted in other countries, including Canada. The purpose of the SRP is to ensure the quality and uniformity of staff safety reviews and to make the review process more transparent. For this reason, the SRP is public in the United States, and proponents can see in advance the criteria against which their submissions will be reviewed and the level of information needed; see [USNRC1987].

6.2.1.4 Licensing process

It is beyond the scope of this chapter to describe the U.S. licensing process in detail. The following description is highly abbreviated; the reader is referred to [USNRC2009] for more detail.

We have already described in Section 5 aspects of an alternative licensing approach in the United States governed by 10 CFR Part 52 that includes options for:

- Early site permits that enable an applicant to obtain approval for a reactor site without specifying the design of the reactor(s) that could be built there;
- Certified standard plant designs which can be used as pre-approved designs;
- A licence which combines a construction permit and an operating licence with conditions for plant operation.

However, at the time this chapter was written (early 2014), all operating plants in the United States have been licensed under a two-step process defined in 10CFR50:

- A construction licence for a particular plant design at a particular site. This process includes submission of relevant information on design, safety analysis, intended operation, the site, the environment, and emergency planning; review by NRC staff, who issue a Safety Evaluation Report summarizing the anticipated effect of the proposed facility on public health and safety; and a public hearing, conducted by the Atomic Safety and Licensing Board (see Section 6.2.1.2).
- An operating licence. This process includes submission of final design and safety information by the applicant and review by the USNRC, who prepare a Final Safety Evaluation Report. A public hearing is not mandatory or automatic, but can be requested by members of the public whose interests might be affected by the issuance of the licence.

In parallel, the licence applications are reviewed by the ACRS (see Section 6.2.1.2), who provide the Commission with independent expert advice.

The entire process is remarkably open, with all documents and correspondence related to the application placed in publicly accessible paper and electronic repositories[9]. This includes the plant Safety Report, the NRC Safety Evaluation Reports, letters between the NRC and the applicant, records of meetings, and other documents. The NRC also holds numerous public meetings during the licensing process.

In addition, conditions may be placed on the licence, which have the same legal force as the licence itself. A generic set of conditions is described in 10CFR § 50.54, "Conditions of licenses". Many areas are covered, e.g., quality assurance, minimum staffing levels, licence amendment or revocation, responsibility of the operator, process for making changes, security, and emergency planning.

Finally, the USNRC has the authority to impose penalties for violations of regulatory requirements. It uses three primary enforcement sanctions:

1. Notice of Violation: This identifies a requirement and how it was violated and normally requires a written response.
2. Civil Penalties: A civil penalty is a monetary fine up to $130,000 per violation per day.
3. Orders: Orders modify, suspend, or revoke licenses or require specific actions by licensees or persons.

6.2.2 United Kingdom

Unlike the United States, the United Kingdom has a very different legal structure, and the regulator has had to license a wide variety of reactor types (gas-cooled reactors, fast reactors, heavy-water reactors, and light-water reactors). This task has been accompanied by a less prescriptive approach.

6.2.2.1 Organization

The Office for Nuclear Regulation (ONR) is responsible for all nuclear regulation in the United Kingdom. It was formed on April 1, 2011, as an agency of the Health and Safety Executive (HSE). ONR combined the safety and security functions of HSE's former Nuclear Directorate, including Civil Nuclear Security, the U.K. Safeguards Office, and the Radioactive Materials Transport team. In turn, HSE is a non-departmental public body (NDPB), which is defined as a "body which has a role in the processes of national Government, but is not a Government Department or part of one, and which accordingly operates to a greater or lesser extent at arm's length from Ministers" [UK2009]. It is sponsored by the Department for Work and Pensions. At the top level, it has a Board, which also contains its Executive Management Team. The work is organized along program lines, as shown in simplified form in Figure 5.

On April 1, 2014, ONR became a Public Corporation under the 2013 Energy Act. ONR is now the enforcing authority for licensed sites in Great Britain, as well as the licensing authority.

9 Some records are not disclosed, e.g., records which must be kept secret in the interest of national defence or foreign policy; internal personnel records; trade secrets and commercial or financial information; records compiled for law-enforcement purposes. For a comprehensive list, see 10CFR § 9.17, "Agency records exempt from public disclosure".

6.2.2.2 Regulatory philosophy

One of the underpinnings of U.K. nuclear safety philosophy is the concept of "so far as is reasonably practicable", or SFAIRP. This was introduced in the Health and Safety at Work Act of 1974 [UK1974], Section 2-(1), and applies to all industry, not just nuclear:

> 2.-(1) It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety, and welfare at work of all his employees."

For this concept, HSE uses the term As Low as Reasonably Practicable (ALARP) and states that [HSE2006]:

> "for assessment purposes, the terms ALARP and SFAIRP are interchangeable and require the same tests to be applied. ALARP is also equivalent to the phrase 'as low as reasonably achievable' (ALARA) used by other bodies nationally and internationally".

ALARA is discussed in Chapter 12. However, the implementation and emphasis in regulatory practice of ALARA and ALARP can be very different. ALARP places the onus on the nuclear-plant designer and operator to justify why further improvements to all aspects of safety cannot be practicably achieved, and in the authors' experience goes considerably beyond ALARA in its scope.

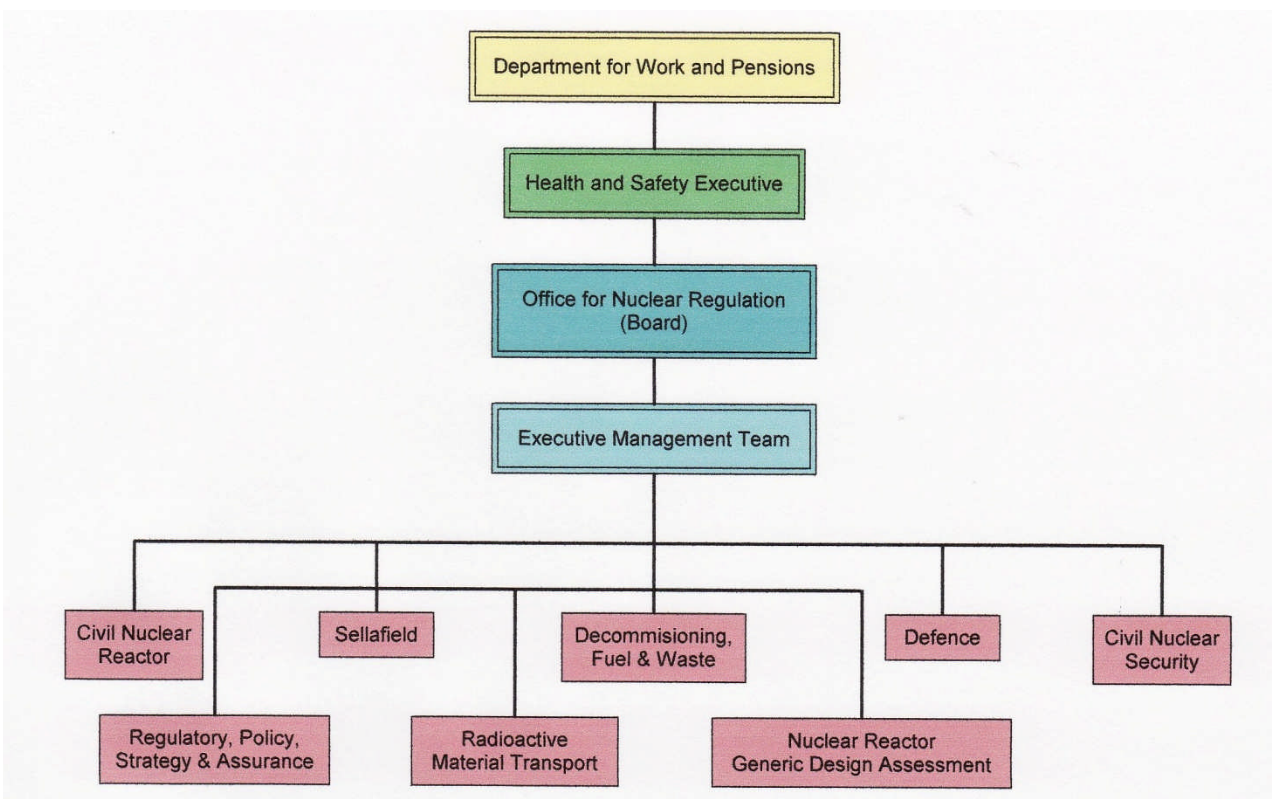

Figure 5 Structure of the ONR

A second underpinning is the concept of acceptable risk. In 1967, Farmer [Farmer1967] proposed a risk-based criterion for use in siting a nuclear reactor. Figure 6 shows his proposed iodine-131 release curve in an accident, versus reactor-years between releases (i.e., the inverse of accident frequency). The basis of the curve was the predicted health effects of an accident, which (if the criterion was met) would be small compared to other social risks. The flattening at the top was to minimize the frequency of small releases due to their nuisance value.

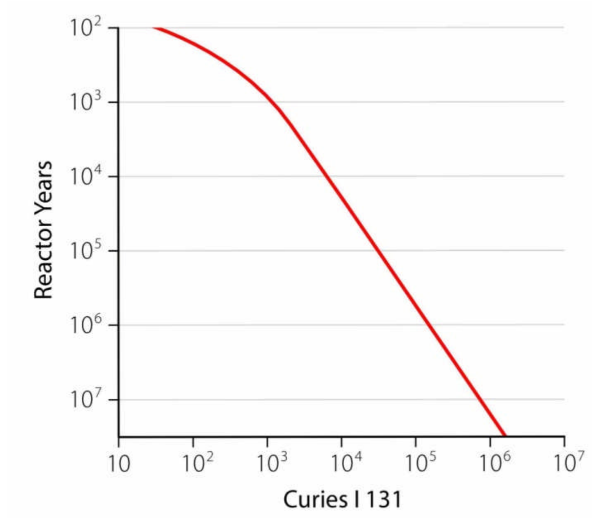

Figure 6 "Farmer" curve

6.2.2.3 Tolerability of risk

This approach developed in the United Kingdom into a risk-based approach along with high-level requirements. These are described in three key documents:

1. The Tolerability of Risk from Nuclear Power Stations [HSE1992];
2. Reducing Risks, Protecting People [HSE2001];
3. Safety Assessment Principles (SAPs) [HSE2006].

The concept evolved from a go/no-go risk line as proposed by Farmer to three distinct regions as shown in

Figure 7. At the top, the risk of the activity is too high regardless of the benefits. At the bottom, the risks are broadly acceptable, and no further reduction is usually required unless reasonably practicable. The middle region of tolerable risk is typical of the risks from activities that people are prepared to tolerate to secure benefits. ALARP would be applied to outcomes in this region.

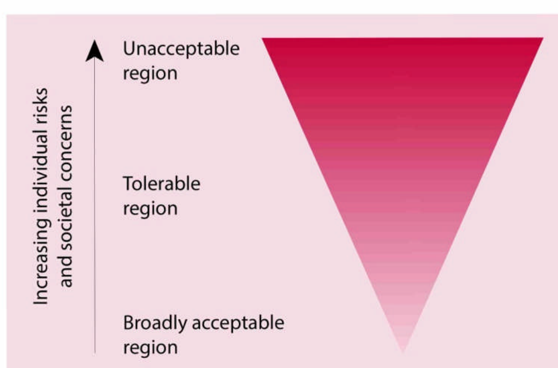

Figure 7 HSE concept of tolerable risk

The risk boundaries are set as follows:

Boundary between "tolerable" and "unacceptable" regions for risk entailing fatality:
Worker: 1 in 1000 /y

Member of the public: 1 in 10,000 /y
This is called the Basic Safety Limit (BSL).
Boundary between "broadly acceptable" and "tolerable" regions for risk entailing fatality:
Worker: 1 in 1,000,000 /y
Member of the public: 1 in 1,000,000 /y
This is called the Basic Safety Objective (BSO).

ALARP is applied in this region between the BSL and the BSO to see if it is reasonably practicable to reduce the risks below the BSO.

These risk targets are applied to all industries in the United Kingdom. For nuclear power, they are translated in the SAPs to BSL/BSOs for normal operation and accidents. The latter become numerical acceptance criteria and targets for the plant PSA. For example, for off-site doses, Table 2 gives typical frequency/dose targets.

Table 2 U.K. frequency / dose targets for accidents off-site

Frequency dose targets for accidents on an individual facility – any person off the site		Target 8
The targets for the total predicted frequencies of accidents on an individual facility, which could give doses to a person off the site, are:		
Effective dose, mSv	**Total predicted frequency per annum**	
	BSL	**BSO**
0.1 – 1	1	1×10^{-2}
1 – 10	1×10^{-1}	1×10^{-3}
10 – 100	1×10^{-2}	1×10^{-4}
100 – 1000	1×10^{-3}	1×10^{-5}
> 1000	1×10^{-4}	1×10^{-6}

The reader should consult [HSE2006] for the full set of numerical targets.

6.2.2.4 Safety assessment principles

The SAPs consist of a set of high-level principles, followed by a large number of technical principles covering the plant life cycle. Although they are expected to be followed by a proponent, they are not legally mandatory (unless they refer to a legal requirement), and are officially written to guide regulatory staff in their assessment of a safety case. They are generally consistent with IAEA Safety Requirements. Most SAPs are followed by a brief explanation or commentary.

It is outside the scope of this chapter to cover these principles in depth (SAPs consisted of 140 pages as of 2006). Appendix A (Section 12) shows some examples of SAPs.

6.2.2.5 Technical assessment guides

The SAPs are supplemented by a series of Technical Assessment Guides (TAGs), which provide more detailed guidance to regulatory staff and fill a similar role to the U.S. Standard Review Plan. Like the latter, they are public.

6.2.2.6 Nuclear site licence conditions

Finally each licensed plant has a series of 36 Standard Conditions attached to its licence, covering design, construction, operation, and decommissioning [ONR2011]. For example, a number of conditions cover changes to the plant during construction and operation and the need for HSE approvals. Because they are attached to the licence, they give HSE a powerful compliance tool.

7 Nuclear Material Safeguards

IAEA and CNSC material has been used throughout this section and referred to specific documents where appropriate. *Italic* fonts have been used to indicate where statements from IAEA or CNSC documents have been used essentially verbatim.

Previous sections have focussed on the "why" of regulatory approaches and have been relatively high-level. The remainder of this chapter provides more detail on safeguards and security and on the Canadian regulatory approach. It is intended to be a guide to the practitioner in finding and understanding relevant requirements, and for Canada, it provides a concise and unique regulatory roadmap. Because regulatory requirements can affect design and operation in a significant way, regulators and the IAEA spend much time making each sentence as precise as possible, much as one does in drafting legislation. For that reason, we have avoided paraphrasing regulatory requirements as much as practicable, instead quoting directly from the relevant documents.

Nuclear material safeguards are enforced around the world by the International Atomic Energy Agency (IAEA). IAEA safeguards are measures through which the IAEA seeks to verify that nuclear material is not diverted from peaceful uses. States that have signed an agreement with the IAEA (which are then considered to be nations committed to the peaceful use of nuclear energy) accept the application of safeguards measures through the conclusion of safeguards agreements with the IAEA [IAEA2007]. There are various types of safeguards agreements, but the vast majority of countries have agreed not to produce or acquire nuclear weapons and to place all their nuclear material and activities under safeguards to enable the IAEA experts to verify that they are complying with the agreements. The origins of the IAEA and of safeguards are discussed in Chapter 13.

7.1 Objectives and Evolution

IAEA safeguards implementation started more than 50 years ago and has been subject to continuous evolution and improvement [IAEA1998], mainly from lessons learned over time.

Safeguards have gone through three major phases [IAEA1998], [IAEA2002d], [IAEA2007b]. The first phase began in the late 1950s and 1960s as nations started to trade in nuclear plants and fuel. The safeguards at that time were designed mainly to ensure that this trade did not lead to the spread of nuclear weapons. The second phase, from 1971 to 1991, reflected a growing perception that, "pending nuclear disarmament, world security is better served with fewer rather than more nuclear weapons and nuclear weapon states". The third and most recent phase, from 1991 to 1997, consisted of a far-reaching review designed to remedy shortcomings in the 1971 system. The review culminated in approval of a significantly expanded legal basis of IAEA safeguards. Figure 8 shows highlights of safeguards evolution from 1991 to the present time.

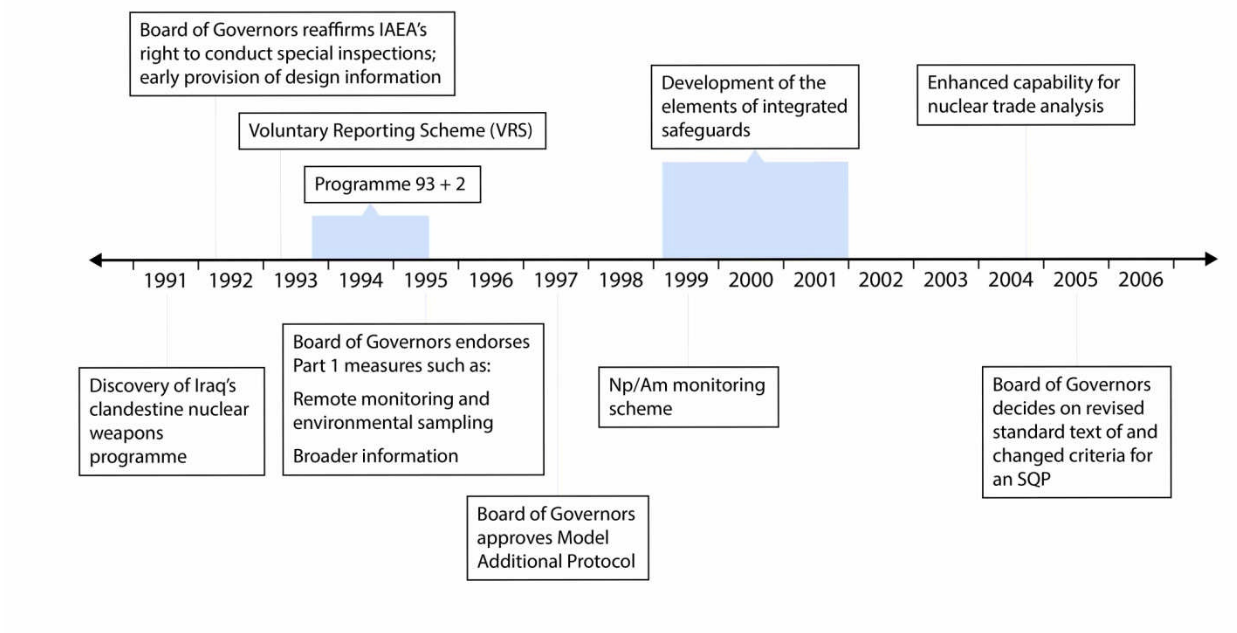

Figure 8 Safeguards state evaluation is a continuous process [IAEA2007b]

One should distinguish between the aims that safeguards seek to achieve in the non-nuclear-weapon and in the declared nuclear-weapon states. The safeguards objectives in the non-nuclear-weapon states are:

- To provide assurance that non-nuclear-weapon states party to comprehensive safeguards agreements are complying with their obligations not to acquire nuclear weapons or other nuclear explosive devices;
- To deter states that have renounced nuclear weapons from acquiring unsafeguarded nuclear material[10]. Safeguards must therefore be effective to detect within a reasonable time the diversion or clandestine production of nuclear material;
- To verify certain facilities and material in some non-nuclear-weapon states with significantly developed nuclear programs, but which have not yet concluded comprehensive safeguard agreements, and therefore are at high risk of proliferation activities. These states are placed under safeguards to prevent them from acquiring nuclear-weapon capability.

The objectives of safeguards related to the formally recognized nuclear-weapon states are:

- To commit not to use nuclear energy to further any military purpose;
- To refrain from any explosive use of nuclear energy;
- To discourage any proliferation of nuclear material that is potentially useful for developing nuclear weapons;
- To encourage widespread acceptance and implementation of safeguards.

10 Note that "nuclear material" includes all fissionable isotopes that can be used as nuclear fuel or explosive material, whereas "non-nuclear material" includes all material of strategic importance, such as heavy water, zirconium tubes, etc.

The technical aim of safeguards is to use technical means to detect and verify safeguards implementation and to provide for reporting of deviations.

For further background, see [IAEA1983], [IAEA1998a], [IAEA2011a], [IAEA2011b], [IAEA2007b].

7.2 Safeguards Treaty Detection Fundamentals

The Treaty on the Non-Proliferation of Nuclear Weapons (the Non-Proliferation Treaty, or NPT) is a cornerstone of the nuclear non-proliferation regime and the basis for implementation of safeguards. It was opened for signature in 1968 and entered into force in 1970. By December 2001, the NPT was in force in 187 states. In 1995, the NPT was extended indefinitely. For details, see [IAEA2002d].

The key requirements of the NPT are:

- Not to receive and transfer any nuclear weapons or nuclear explosive devices, or control of such weapons or devices directly or indirectly;
- Not to manufacture or otherwise acquire such weapons or devices;
- Not to seek or receive any assistance in development or manufacture of such devices;
- To accept IAEA safeguards on all fissionable material in peaceful nuclear activities;
- Not to provide source or special fissionable material, or equipment or material especially designed or prepared for the processing, use or production of special fissionable material to any non-nuclear-weapon State;
- To sign safeguard agreements with the IAEA either individually or together with other States within 18 months of the date on which the State deposits its instruments of ratification of or accession to the NPT Treaty
- Allows each State party to the NPT Treaty to develop research, production, and use of nuclear energy for peaceful purposes and to facilitate and participate in the fullest possible exchange of equipment, materials, and information for the peaceful uses of nuclear energy.

7.3 Safeguard Approaches, Concepts, and Measures

The key requirement for a successful safeguards program is to collect sufficient information from various sources [IAEA2007]. The main sources of safeguards information are:

1. State-supplied information (under the obligation of the safeguards treaties and agreements)
    a. Nuclear material accountancy and facility design
    b. Voluntary reported information
    c. Additional protocol declarations
2. Key results of verification activities
    a. Inspection
    b. Design information verification (DIV)
3. Other information coming from open and other sources

In the first and second phases of the safeguard evolution process (until the early 1990s) the focus of the safeguards program was limited to the Comprehensive Safeguards Agreement protocols, which included:

a. Fuel enrichment facilities

b. Fuel fabrication facilities
c. Nuclear reactors
d. Spent fuel storage
e. Reprocessing facilities.

The Generic safeguards approach specifies the IAEA goals and safeguard activities for a reference plant. The Facility safeguards approach is prepared for a specific facility, developed and adjusted to specific facility characteristic features and activities. The State-level safeguards approach is developed for a specific state, encompassing all nuclear material, nuclear installations, and nuclear activities.

The integrated safeguards approach, which is a variation of the State-level safeguards approach, was developed as an optimum combination of all safeguards measures available to the IAEA under comprehensive safeguard agreements and additional protocols. Starting in the early 1990s, the safeguards program was extended, and is known today as Broad Overview of Expanded Safeguards Coverage Protocols, which in addition to the above targets, include the following:

a. Equipment manufacturers
b. Mining and milling
c. Conversion facilities
d. R&D centres.

The nuclear material accountancy within the framework of IAEA safeguards begins with the nuclear-material accounting activities by facility operators and the state system of accounting for and control of nuclear materials. *The IAEA implements nuclear accountancy at various levels [IAEA2002d]:*

1) At the Facility Level by:
   a) Dividing operations into nuclear material balance areas (MBAs);
   b) Maintaining records on nuclear material quantities in each MBA;
   c) Measuring and recording all transfers of nuclear material from each MBA to another area or facility;
   d) Periodically determining quantities of nuclear material in each MBA;
   e) Closing the material balance over the period between two successive physical inventory takings and computing the material unaccounted for (MUF);
   f) Providing for a measurement control program to determine the accuracy of calibrations and measurements;
   g) Testing the computed MUF against its limits or errors in the accidental loss of gain;
   h) Analysing the collected accounting information to determine the cause and magnitude, and taking lessons learned for future improvements.
2) At State Authority Level
   a) Preparing and submitting nuclear material accounting reports to the IAEA;
   b) Ensuring that nuclear material accounting procedures and arrangements are adhered to;
   c) Providing for IAEA inspector access and co-ordination arrangements;
   d) Verifying facility operators' nuclear material accountancy performance.
3) At IAEA Level by:
   a) Independently verifying nuclear material accounting information in facility records and State records, and conducting activities as per safeguard agreements signed with the

State;

b) Determining the effectiveness of the State safeguards program;
c) Providing statements to the State about the IAEA verification activities.

7.4 Safeguards Design Implications for Nuclear Power Plants

Most safeguards attention is devoted to nuclear power plants (NPPs) ([IAEA1998a], [IAEA2014]).. NPPs are subject to a large flow of nuclear materials. At both off-load refueled LWRs and on-load refueled PHWRs, the entire facility constitutes one MBA. Therefore, all activities at the NPP site are under the safeguards monitoring program.

Figure 9 shows the elements of safeguards in a generic NPP facility. The top route in Figure 9 shows the real material storage areas and transfer routes, including the possibilities for diversion as dashed lines. The middle route in Figure 9 represents the nuclear-material accounting by the operator concerning the activities that have occurred. If this declared record of storage status and transfers accurately reflects the real inventories and transfers, then there can be a high degree of confidence that diversion activity has not occurred. The bottom route in Figure 9 represents the IAEA activities in monitoring physical activity in the storage and material-transfer areas for accounting verification purposes. Any activity observed that does not correspond to that declared will initiate a pre-planned process to re-establish confidence that the declared record reflects the real inventory. That process might lead to an examination and validation of the entire inventory, an expensive task which should be avoided.

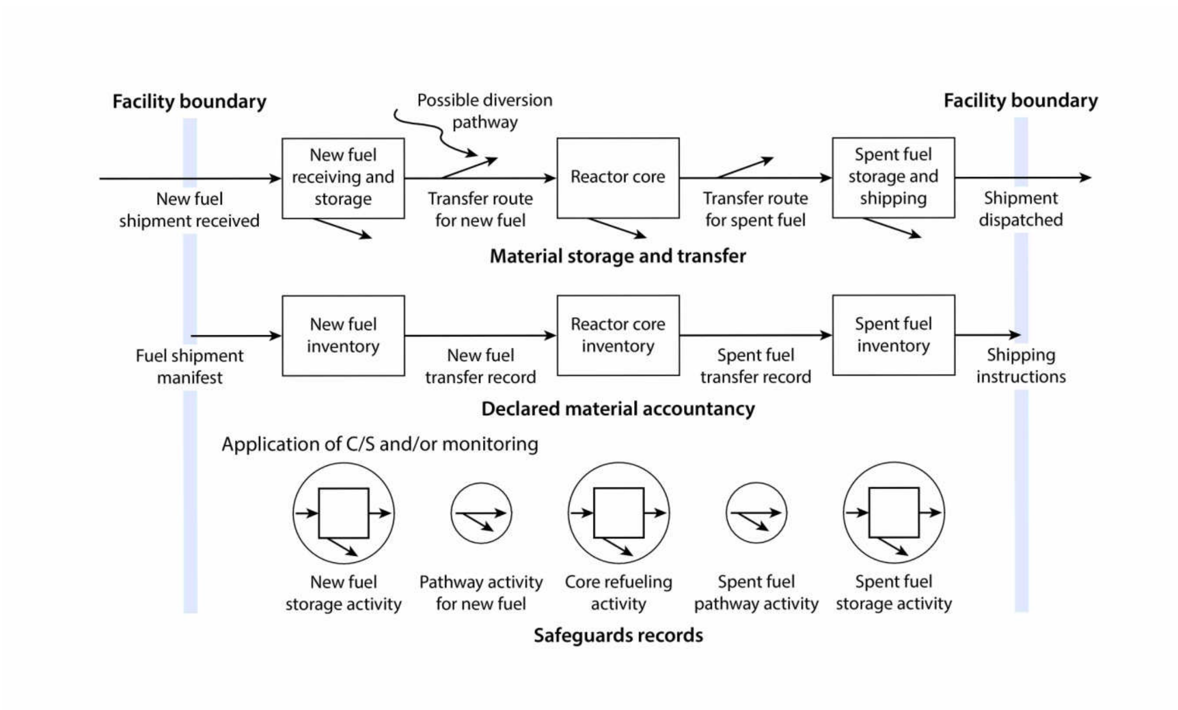

Figure 9 Elements of safeguards [IAEA1998a]

Safeguards approaches, experience, and the associated guidelines vary between off-load and on-load refueled reactors:

a) For off-load refueled reactors, refuelling operations and the associated fuel movements are conducted at low frequency and with large numbers of items moved per refuelling;

b) For on-load refueled reactors, fuel movements and refuelling operations are carried out at high frequency (daily), but with a small number of items moved per refuelling.

LWRs are refueled off-load, refuelling operations occur with an open vessel, and transfers occur in channels filled with transparent water shielding. This design combination permits direct visual observation. Transparent shielding is impractical for refuelling operations in on-load refueled reactors, and therefore observation by other means is required. In these NPPs, detection of variations in radiation fields from continuously operating instrumentation together with optical surveillance provide the information needed on refuelling sequences for safeguard purposes. Regardless of the NPP design, all fuel is properly labelled by visible and non-visible marking to be read by modern optical and laser devices.

Figure 10 shows the position of optical surveillance devices in the reactor building and the fuel-storage pool building in the LWR reactor design.

Application of the general principles for safeguards is common to all pressure-tube PHWRs. Most IAEA experience in handling PHWRs has been obtained on CANDU reactors.

Figure 11 shows the position of optical surveillance devices in the reactor building and the fuel-storage pool building in the CANDU reactor design.

CANDU NPPs have horizontal fuel channels and are heavy-water moderated and cooled. The refuelling system uses two refuelling machines, one at each end of the core, to insert new fuel at one end and to accept spent fuel at the other. CANDU NPPs require appropriate shielding of the refuelling machines and operations to protect personnel. Consequently, the positioning of the fuelling machines in front of the reactor channels, and the refuelling itself, are carried out by remote control.

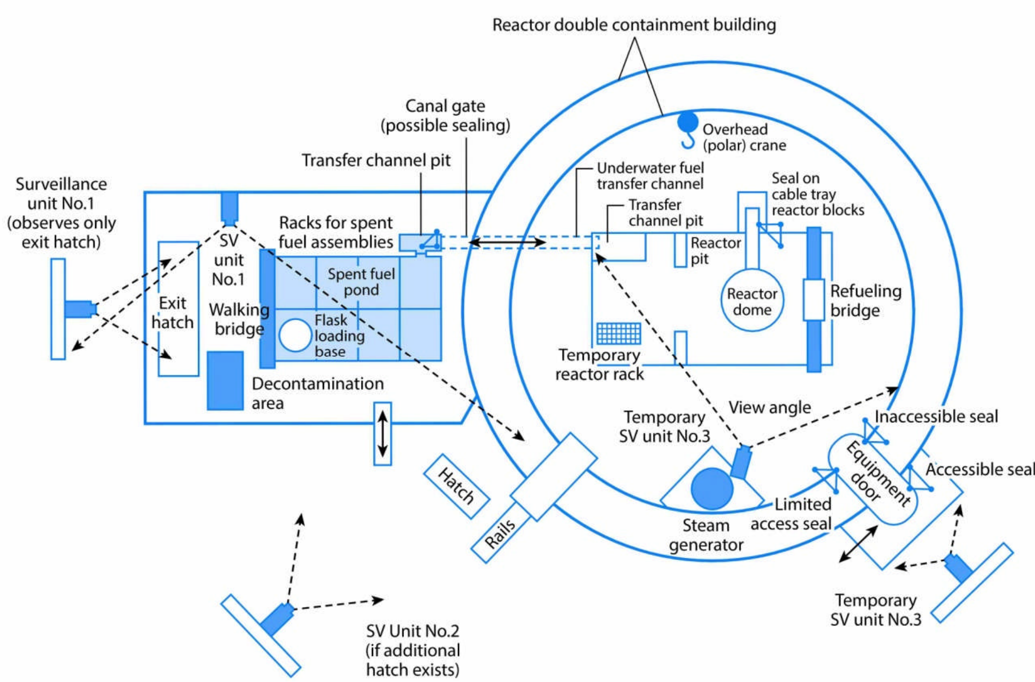

Figure 10 Design aspects of safeguards in LWR reactors (Type II) [IAEA1998a]

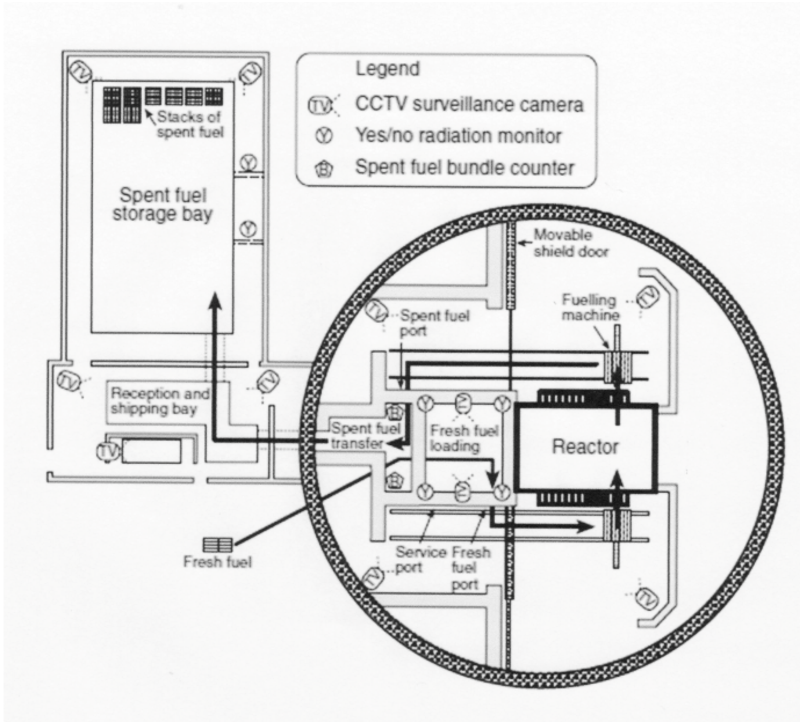

Figure 11 Design aspects of safeguards in CANDU reactors [IAEA1998a]

Item accountancy and maintaining continuity of knowledge using containment and surveillance (C/S) measures form the basis of the CANDU safeguards approach. Direct verification of the operator's declared nuclear material inventory is implemented for fresh and spent fuel. Although fuel bundles in the core remain inaccessible for verification, continuity of knowledge is maintained by a monitoring system when they are discharged. C/S covers the discharge of spent fuel from the reactor and storage in the spent fuel bays to provide continuity of knowledge.

All NPP designer organizations are required to ensure that their designs are safeguards friendly, i.e., the design allows adequate implementation of the safeguards specific approaches. Some of these requirements are listed below (not an inclusive list):

- Requirement for early interaction between the designer and the IAEA;
- Design of barriers which form a part of the C/S system;
- Design of seals for moving nuclear material;
- Design of surveillance techniques;
- Design of fuel identification and fuel verification techniques;
- Detection of unrecorded production or use of nuclear material;
- Transfer for spent fuel from the spent fuel pool to storage or reprocessing.

8 Nuclear Security

Nuclear security has become far more important in the last couple of decades, due largely to changes in the external political environment after the September 11, 2001, terrorist attacks in the United States. Each utility implements security at its sites, and in Canada, regulation of nuclear security is part of the mandate of the CNSC.

Top-level requirements are set by the Nuclear Security Regulations [GovCan2010]. This Act covers the security of both certain nuclear materials and nuclear facilities.

Nuclear materials are divided into three categories related to their security impact: for example, a quantity of non-irradiated plutonium >2 kg is Category I; between 500 g and 2 kg is Category II; and between 15 g and 500 g is Category III. Possession in each category requires a licence, and the security obligations for each case are defined in the regulations.

For nuclear facilities in Canada, it is up to the CNSC Commission to establish and update the design basis threat which is taken into account by the utility in determining its security provisions. In addition, the utility must conduct an annual facility-specific threat and risk assessment. Nuclear facilities must be located within a protected area enclosed by a barrier. Category I materials are further protected by an inner-area structure or barrier whose function is to detect and delay unauthorized access before the on-site nuclear response force can successfully intervene.

In addition, the operator must identify *vital areas*. These are areas inside the protected area containing equipment, systems, devices, or a nuclear substance, the sabotage of which would or would likely pose an unreasonable risk to the health and safety of persons arising from exposure to radiation. The operator is then required to implement the appropriate physical protection measures.

The Act also sets out requirements for persons authorized to enter protected and inner areas and for security personnel. The CNSC has supplemented and expanded the Nuclear Security Regulations through a number of Regulatory Documents and Guides. Most of those pertaining to high-security sites such as nuclear power plants contain prescribed information and are not publicly available, and therefore they are not referenced here.

Further details of security regulations, implementation techniques, and verification methodologies are beyond the scope of this textbook and are not available to the general public.

9 Canadian Regulatory Process[11]

The Canadian regulatory process is based on over 60 years of CANDU reactor development and operation in Canada and internationally. Canada has been in the forefront of nuclear power development and use since the very beginning, including the development of its nuclear regulatory program.

The Parliament of Canada first established legislative control and federal jurisdiction over the development and use of nuclear energy and nuclear substances in 1946 with the introduction of the *Atomic Energy Control Act* (AECA), which also established the Atomic Energy Control Board (AECB). Fifty years later, the Canadian Government updated its regulatory requirements, and the Canadian Nuclear Safety Commission was established as a successor to the AECB.

CNSC material has been used throughout this section. We refer to specific documents where appropriate. As noted earlier, we do not try to paraphrase carefully developed regulatory texts. *Italic* fonts have been used to indicate where statements from CNSC documents have been used essentially verbatim.

11 Some of the descriptive material has been drawn from the Web site of the CNSC over the period from July 2011 to January 2013.

9.1 The CNSC

The Canadian Nuclear Safety Commission regulates the use of nuclear energy and materials to protect the health, safety, and security of Canadians and the environment, and to implement Canada's international commitments on the peaceful use of nuclear energy.

The CNSC develops, maintains, and revises all regulatory requirements and documents under the authority of the Nuclear Safety and Control Act [GovCan2013], which sets the overall legal framework for regulation.

9.2 CNSC Mandate and Organization

This section covers the mandate and role of the CNSC in the Canadian NPP regulatory process. It also covers the key elements of the CNSC organization, starting with the Commission and continuing with the organization of various departments and their role in Canadian regulatory processes.

As discussed in Section 2.3, the CNSC consists of an appointed Commission supported by technical staff.

The CNSC Commission has up to seven appointed permanent part-time members whose decisions are supported by more than 800 staff. These employees review applications for licences according to regulatory requirements, make recommendations to the Commission, and review (and can be delegated by the Commission to enforce) compliance with the Nuclear Safety and Control Act, regulations, and any licence conditions imposed by the Commission.

Under the NSCA [GovCan2013], CNSC's mandate involves four major areas:

- regulation of the development, production and use of nuclear energy in Canada to protect health, safety and the environment
- regulation of the production, possession, use and transport of nuclear substances, and the production, possession and use of prescribed equipment and prescribed information
- implementation of measures respecting international control of the development, production, transport and use of nuclear energy and substances, including measures respecting the non-proliferation of nuclear weapons and nuclear explosive devices
- dissemination of scientific, technical and regulatory information concerning the activities of CNSC, and the effects on the environment, on the health and safety of persons, of the development, production, possession, transport and use of nuclear substances.

The CNSC organization is shown in Figure 12. Note:

- the Regulatory Operations Branch, which is responsible for NPP licensing in Canada;
- the Technical Support Branch, which is home to all the CNSC discipline specialists and experts who review and assess various reactor designs and all information submitted in support of a licence application.

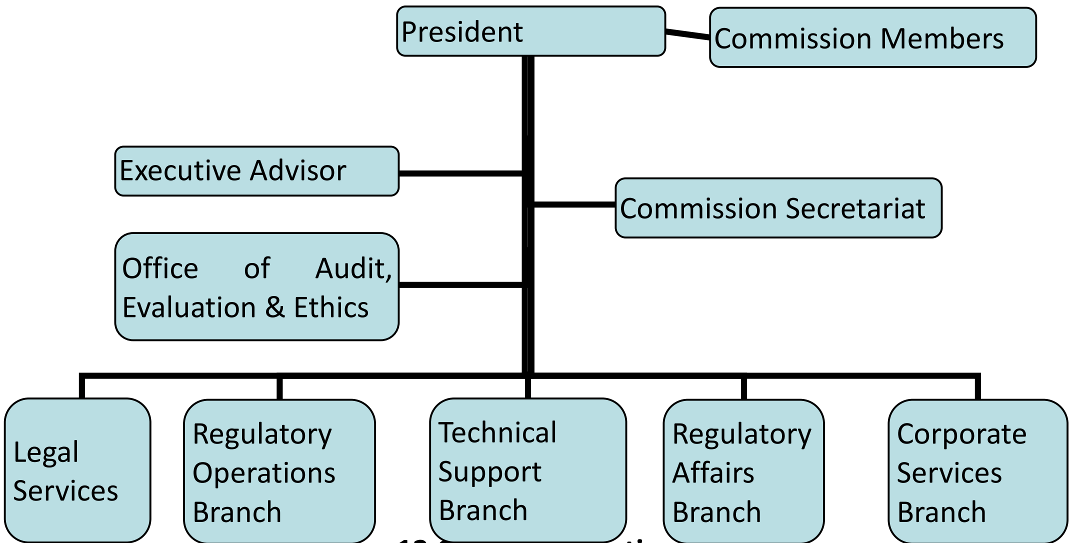

Figure 12 CNSC organization

9.3 Canadian Regulatory Framework and Regulatory Acts

The Canadian regulatory documents are arranged in several levels, as shown in Figure 13, starting at the top level with enabling legislation, then at the middle level with requirements documents, and at the lowest level with guidance documents. The requirements documents can be subdivided into regulations, licences, and regulatory documents (defined in Sections 9.5.1 and 9.5.2).

Three Acts are relevant and are described in the following sub-sections.

9.3.1 Nuclear Safety and Control Act

The Nuclear Safety and Control Act [GovCan2013] is the enabling legislation in Canada, as shown in Figure 13 and as described in Section 9.2.

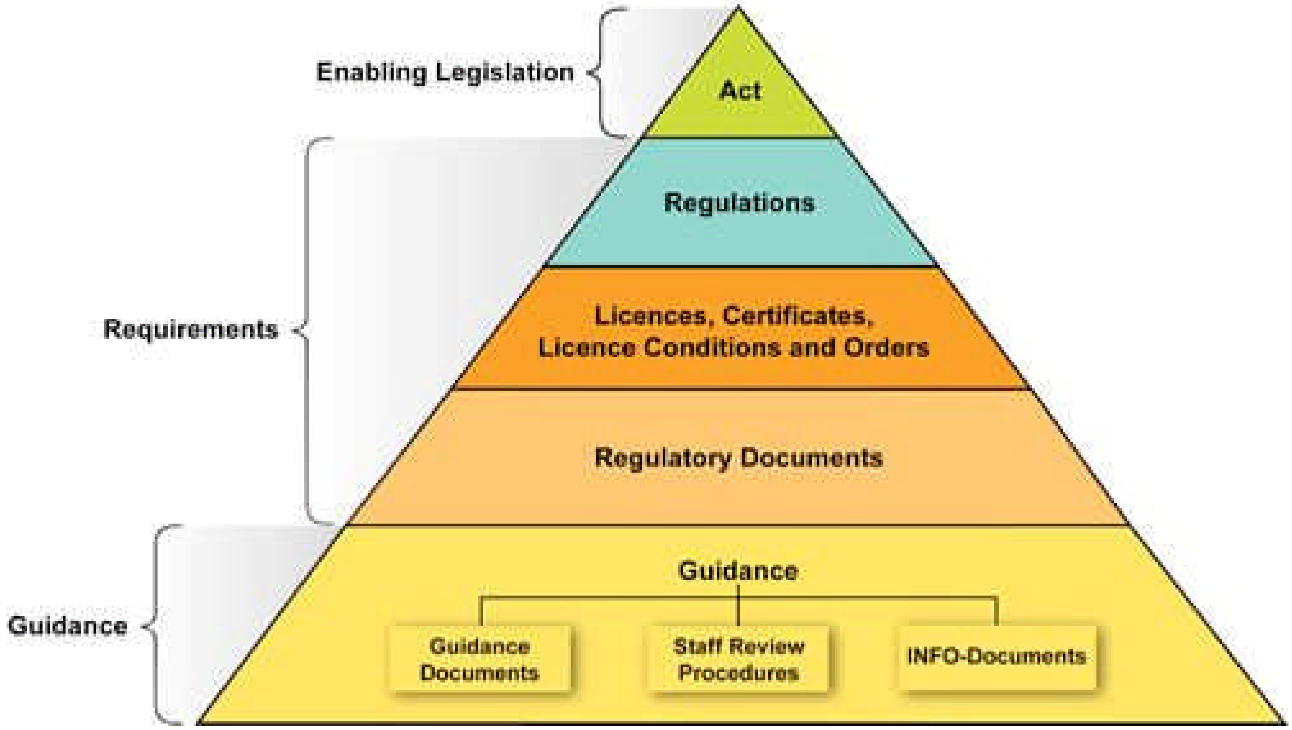

Figure 13 Structure of regulatory documents in Canada

The Act covers the following areas:

- Establishment and organization of the Canadian Nuclear Safety Commission (CNSC);
- Number and role of CNSC members;
- Role, responsibilities, and duties of the CNSC President;
- Directives and powers of the CNSC;
- Use, establishment, and responsibilities of various panels that may be established by the CNSC;
- The decision-making process at the CNSC;
- The scope and process for issuing or revoking various licences to the Canadian industry;
- The responsibilities of the CNSC for maintaining various records and reports;
- Appointment of various specialists, analysts, and inspectors of the CNSC;
- Appointment of designated officers (to whom the Commission can delegate some if its authority to make decisions on its behalf);
- Process for creation of procedures for decisions and orders;
- Process for redetermination and appeal of decisions and orders;
- Scope of regulations and process for their creation and enforcement;
- Provisions for exceptional powers;
- Provisions for offences and punishment;
- Transitional provisions.

Of particular importance is sub-section 24(4) of the Act, which states that:

"No licence shall be issued, renewed, amended or replaced—and no authorization to

transfer one given—unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee:
(a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
(b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons, and the maintenance of national security and measures required to implement international obligations to which Canada has agreed."

The next level in Figure 13 is *Regulations*, which are published in the Canada Gazette and include:

- General Nuclear Safety and Control Regulations [GovCan2008]
- Radiation Protection Regulations [GovCan2007]
- Class I Nuclear Facilities Regulations [GovCan2012a]
- Class II Nuclear Facilities and Prescribed Equipment Regulations
- Uranium Mines and Mills Regulations
- Nuclear Substances and Radiation Devices Regulations
- Packaging and Transport of Nuclear Substances Regulations
- Nuclear Security Regulations [GovCan2010]
- Nuclear Non-Proliferation Import and Export Control Regulations [GovCan2010a]
- CNSC Cost Recovery Fees Regulations
- Administrative Monetary Penalties Regulations
- Canadian Nuclear Safety Commission Rules of Procedure
- Canadian Nuclear Safety Commission By-Laws

We have provided references above for some of the key Regulations in the nuclear power-reactor field.

In addition, when required, the CNSC puts forward proposals for new regulations or proposed amendments to existing regulations:

- Regulations Amending the Class I Nuclear Facilities Regulations and the Uranium Mines and Mills Regulation
- Amendments to Nuclear Non-Proliferation Import and Export Control Regulations
- Amendment to Class II Nuclear Facilities and Prescribed Equipment Regulations
- Regulations Amending Certain Regulations made under the Nuclear Safety and Control Act (Miscellaneous Program)
- Amendments to the Packaging and Transport of Nuclear Substances Regulations.

9.3.2 Canadian Environmental Assessment Act

The second relevant Act is the Canadian Environmental Assessment Act [GovCan2012], which covers all aspects of the environmental assessment process that must be followed for a new nuclear energy facility of any purpose and type. It sets out the requirements for addressing all important environmental issues, radiological and non-radiological.

9.3.3 Canadian Nuclear Liability Act

The third Act is the Canadian Nuclear Liability Act [GovCan1985], which regulates the nuclear responsibility of various participants in the Canadian nuclear industry. The underlying purpose of the Act is to require nuclear operators to carry insurance to cover liability should an accident occur. The operator is absolutely liable for damage irrespective of the cause of the accident: that is, claimants do not have to prove negligence on the part of the operator—they need only prove that they have suffered damage. Operators must obtain liability insurance for damages up to a maximum of $75 million (but see next paragraph); if the consequences exceed that amount, the federal government appoints an independent Nuclear Damage Claims Commission that will receive claims, assess damages, and recommend the level of compensation that should be paid. The responsibility to pay claims exceeding $75 million rests with the federal government. The Act does not set a limit on what the government pays.

As of this writing (early 2014), Bill C-22 (the Energy Safety and Security Act) has been tabled in the House of Commons to replace the Nuclear Liability Act. It raises the absolute liability limit to $1 billion for both nuclear energy and offshore oil and gas. It is expected that this bill will be enacted by the House of Commons.

9.3.4 Other acts

Other Acts that pertain to some aspects of nuclear power plants include:

- Canadian Environmental Protection Act
- Fisheries Act
- Species at Risk Act
- Navigable Waters Protection Act
- Transportation of Dangerous Goods Act.

9.4 Licences

The third level in Figure 13 also includes *licences*. These are mandatory legal documents which set forth the requirements and limitations for activities undertaken during the life cycle of a nuclear activity. For example, a Power Reactor Operating Licence typically covers (among other items):

- Authorization to operate the nuclear power plant for a specified period;
- Reporting of events to the CNSC;
- Control of the exclusion zone within which no permanent dwelling is permitted and temporary access is controlled;
- References to some of the CNSC Regulatory Documents listed in Section 9.5, which therefore become mandatory;
- References to some of the CSA Standards listed in Table 6, which therefore become mandatory;
- Maintaining minimum operating-crew size and composition, including obtaining operating licenses for key staff;
- Complying with the requirement to use a set of Operating Policies and Principles, including Operating Limits;
- Complying with reactor power limits, including bundle and channel power limits
- Limits on permissible changes without CNSC prior consent. Specifically, this forbids changes which “introduce hazards different in nature or greater in probability than those considered by the Final Safety Analysis Report and Probabilistic Safety Assess-

ment". Such a clause binds the results of the safety assessment performed by the operator to the licence;
- Using only those fuel-bundle designs approved by the CNSC;
- Complying with requirements for an emergency plan for the facility;
- Complying with the limits on releases of radioactive material in normal operation (derived release limits);
- Following requirements for a maintenance program; and
- Complying with requirements for radiation protection, site security, and safeguards.

The licence is accompanied by, and references, a rather lengthy "Licence Conditions Handbook", which provides:

- compliance verification criteria to meet the conditions listed in the licence;
- information regarding delegation of authority and current versions of documents;
- implementation timelines for specific licence conditions; and
- an explanation of each regulatory requirement specified in the licence.

In effect, the Licence Conditions Handbook extends the scope of the licence.

9.5 CNSC Regulatory Documents

The fourth level in Figure 13 contains the Requirements Documents. They are not *legally* mandatory until and unless referenced in a licence. They are *effectively* mandatory for new designs and are used as an evaluation tool for existing designs.

The fifth level in Figure 13 contains the Guidance Documents. These documents provide direction to licensees and applicants on how to meet the requirements set out in the CNSC's Regulations, regulatory documents, and licences, and the techniques used by CNSC staff to evaluate specific problems or data needed in the review of applications for permits or licences.

The following sub-sections provide a basic explanation of key CNSC regulatory and guidance documents.

9.5.1 Historical classification schemes

The CNSC documents have followed several labelling and numbering schemes that reflect the different periods when these documents were created. We review the historical schemes briefly because many of these documents are still referenced under their original names in licences.

Originally the AECB issued all requirements documents as "R" ("regulatory") documents.

This system was superseded by the following classification:

- "S" ("Standard") documents, which were mandatory
- "G" ("Guidance") documents, which provided guidance
- "P" ("Policy") documents, which provided direction to CNSC staff and information for stakeholders.

More recently, CNSC has used the labels "RD" (Regulatory Document) and "GD" (Guidance Document). Occasionally, CNSC has issued documents as "RD/GD", which means that some parts of the document contain (effectively) requirements and other parts contain guidance. In such cases, CNSC staff clarifies when information is mandatory.

The "RD" and "GD" labels have now been replaced by "REGDOC", as discussed in Section 9.5.2.

In CNSC regulatory documents, "shall" is used to express a requirement, i.e., a provision that a licensee or licence applicant is obliged to satisfy to comply with the requirements of the document. "Should" is used to express guidance, or that which is advised, but not required. "May" is used to express an option or that which is permissible within the limits of the document. "Can" is used to express possibility or capability.

9.5.2 Current classification scheme

The CNSC has recently developed a classification scheme (by subject) for its existing and planned regulatory documents. As of April 2013, all these documents are now organized under three key categories and twenty-five series as follows:

1.0 Regulated facilities and activities

1.1 Reactor facilities

1.2 Class IB facilities

1.3 Uranium mines and mills

1.4 Class II facilities

1.5 Certification of prescribed equipment

1.6 Nuclear substances and radiation devices

2.0 Safety and control areas

2.1 Management system

2.2 Human performance management

2.3 Operating performance

2.4 Safety analysis

2.5 Physical design

2.6 Fitness for service

2.7 Radiation protection

2.8 Conventional health and safety

2.9 Environmental protection

2.10 Emergency management and fire protection

2.11 Waste management

2.12 Security

2.13 Safeguards and non-proliferation

2.14 Packaging and transport

3.0 Other regulatory areas

3.1 Reporting requirements

3.2 Public and aboriginal engagement

3.3 Financial guarantees

3.4 Commission proceedings

3.5 Information dissemination

The numbering scheme used in this categorization is “REGDOC-x.yy.zz”, where “x” is the number of the key category, “yy” is the number of the series, and “zz” is a number which identifies the document uniquely within that category and series. For example, the design requirements for new reactor designs are documented in REGDOC-2.5.2, where the first “2” means the document is in the “safety and control area”; “5” means it is under the “physical design” series; and the last “2” is a sequence number identifying the specific document.

9.5.3 Licensing basis

Many of these documents form the licensing basis of a regulated facility or activity. The *licensing basis* [CNSC2010a] is a set of requirements and documents consisting of:

a) Regulatory requirements set out in the applicable laws and regulations.

- Examples: the Nuclear Safety and Control Act, the Canadian Environmental Assessment Act, the Canadian Environmental Protection Act, the Nuclear Liability Act, the Transportation of Dangerous Goods Act, the Radiation Emitting Devices Act, the Access to Information Act, and the Canada/IAEA Safeguards Agreement.

b) Conditions and safety and control measures described in the facility licence and the documents directly referenced in that licence.

- Examples: the Nuclear Security Regulations, the Nuclear Non-Proliferation Import and Export Control Regulations, the General Nuclear Safety and Control Regulations, the Radiation Protection Regulations, the Uranium Mines and Mills Regulations, the Class I Nuclear Facilities Regulations, the Nuclear Substances and Radiation Devices Regulations, the Class II Nuclear Facilities and Prescribed Equipment Regulations, and the Packaging and Transport of Nuclear Substances Regulations.

c) Safety and control measures described in documents directly referenced in the licence.

- Examples: regulatory documents (such as RD-204, RD/GD-210, S-294, plus others), industry codes and standards (such as CSA N286-05, CSA N285.4, CSA N290.13), proponent- or licensee-produced documents, and any subsequent changes made to these documents in accordance with a CNSC-approved change control process (such as Management System Manual, Limits and Conditions of Operation).

d) Documents needed to support the licence application.

- Examples are documents describing the design, safety fuellings, and all aspects of operation to which the licensee makes reference; conduct of operations; and conduct of maintenance.

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity and thus establishes the basis for the CNSC's compliance program with respect to that regulated facility or activity.

We now summarize selected regulatory documents. Note that document numbers and titles are shown in terms of the currently issued documents (and not in terms of the new classification scheme shown in Section 9.5.2).

9.5.4 Design of new NPPs in Canada: RD-337

RD-337 [CNSC2008] sets out comprehensive CNSC requirements with respect to the design of new water-cooled NPPs and provides examples of optimal design characteristics[12]. Excerpts follow:

> The information provided in this document is intended to facilitate high quality design, and consistency with modern international codes and standards, for new water-cooled NPPs. It is recognized that specific technologies may use alternative approaches. If a design other than a water-cooled reactor is to be considered for licensing in Canada, the design is subject to the safety objectives, high level safety concepts and safety management expectations associated with this regulatory document.
> To a large degree, this document represents the CNSC's adoption of the principles set forth in International Atomic Energy Agency (IAEA) document NS-R-1, Safety of Nuclear Plants: Design, and the adaptation of those principles to align with Canadian practices. The scope of NS-R-1 has been expanded to address the interfaces between NPP design and other topics, such as environmental protection, radiation protection, ageing, human factors, security, safeguards, transportation, and accident and emergency response planning.

The main components of RD-337 are:

i. Safety objectives and concepts
This section covers safety objectives in Canada (general, radiation protection, and technical), safety goals, radiation dose criteria, accident mitigation and management, and safety concepts (defence-in-depth, physical barriers, and operating limits and conditions).
ii. Safety management during design
This section discusses safety during the design process. It includes all important aspects of the design process, including design authority, design management, QA, proven engineering practices, design documentation, etc.
iii. Safety considerations
This section covers all aspects of safety applications in a design, including the application of defence-in-depth, safety functions, accident prevention and plant safety characteris-

12 While this Chapter was being finalized, CNSC issued an update to RD-337 – called REGDOC 2.5.2 – which adds lessons learned from Fukushima. See [CNSC2014].

tics, radiation protection principles and acceptance criteria, exclusion zones, and facility layout.

iv. General design considerations

This section contains general requirements for all technical disciplines and reactor engineering areas. It covers:

- structure, system, and component classifications;
- plant design envelope and operating plant states;
- guidance for consideration of all important hazards and initiating events that need to be considered in the design;
- design rules, limits, and reliability for safety (such as common-cause failures, single failures, fail-safe requirements, etc.);
- pressure-retaining systems and components;
- equipment classification (seismic, fire, environmental, etc.);
- instrumentation and control;
- safety support systems;
- civil structures;
- human factors;
- commissioning;
- security;
- safeguards;
- decommissioning.

v. System-specific requirements

This section covers requirements specific to most important systems and functions, including the reactor core, heat-transport system, steam-supply system, means of shutdown, emergency core cooling system, containment, emergency power supply, heat transfer to an ultimate heat sink, emergency heat-removal system, control facilities, waste management and control, fuel handling and storage, and radiation protection.

vi. Safety analysis

The safety analysis sections cover the most important aspects of safety analysis, namely analysis objectives, hazards analysis, deterministic analysis, and probabilistic analysis. The topic is covered in RD-310 in more detail [CNSC2008b].

vii. Environmental protection and mitigation

This section covers environmental protection design and requirements, as well as requirements for released radioactive and hazardous substances.

viii. Alternative approaches

RD-337 is intended to be technology-neutral for water-cooled reactor designs. It is recognized that specific technologies may use alternative approaches.

The CNSC considers alternative approaches to the expectations in this document where:

- The alternative approach would result in an equivalent or superior level of safety;
- Application of the expectations in this document conflicts with other rules or requirements;
- Application of the expectations in this document would not serve the underlying purpose, or is not necessary to achieve the underlying purpose; or
- Application of the expectations in this document would result in undue hardship

or other costs that significantly exceed those contemplated when the regulatory document was adopted.

One example of an alternative approach is consideration of best estimate and uncertainty analysis instead of a conservative analysis; see Chapter 13.

9.5.5 NPP site evaluation: RD-346

This regulatory document [CNSC2008c] sets out requirements for the evaluation of sites for new NPPs before an application is made for a Licence to Prepare Site and before an environmental assessment determination is initiated.

RD-346 represents the CNSC staff's adoption, or where applicable, adaptation of the principles set forth by the International Atomic Energy Agency (IAEA) in NS-R-3, Site Evaluation for Nuclear Installations. The scope of RD-346 goes beyond NS-R-3 in several aspects such as the protection of the environment, security of the site, and protection of prescribed information and equipment, which are not addressed in IAEA's NS-R-3.

Site evaluation is a process that should precede the submission of an application to prepare a site for the construction of a new NPP. RD-346 is written to serve the broader licensing needs under the Nuclear Safety and Control Act and the Canadian Environmental Assessment Act, and will facilitate a more effective and efficient regulatory review.

The document covers criteria for site evaluation; type and scope of baseline data required in the site evaluation process; evaluation of natural external events; evaluation of external, non-malevolent, human-induced events; security considerations; decommissioning; quality assurance; and the consultation process.

9.5.6 NPP life extension: RD-360

The regulatory document RD-360 [CNSC2008d] covers the regulatory requirements for NPP life-extension programs. The purpose of this regulatory document is to inform licensees about the steps and phases to consider when undertaking a project to extend the life of a nuclear power plant. The main topics are:

- Key elements to consider when establishing the scope of the life-extension project; and
- Considerations to be taken into account in planning and executing a life-extension project.

The document covers the initiation of the life-extension project, preparation of the integrated project plan (which includes environmental assessment, safety assessment, integrated implementation plan and its adequacy, etc.), project execution, and return to service.

A major part of the assessment for life extension requires reviews of the existing plant against modern codes and standards, including, but not limited to, CNSC documents more recent than were in place at the time the plant was originally licensed. Although compliance is not mandatory, gaps must be identified, assessed, and remedied if practical. In addition, the condition of systems, structures, and components (SSC) is assessed, largely to capture the effects of aging and degradation. These assessments may also identify gaps. The entire assessment is collected in a Global Assessment Report (GAR), from which an Integrated Implementation Plan (IIP) is developed. The IIP is a work plan and schedule to fix the identified gaps insofar as is practical and risk-effective. Such life-extension assessments are similar to, but much broader in scope than, periodic safety reviews.

9.5.7 Safety analysis for NPPs: RD-310 and GD-310

Safety analysis is one of the most important topics in NPP licensing because it provides the assurance that the plant can be operated safely and that the postulated events can be prevented, mitigated, and managed. The CNSC has issued both the requirements document (RD-310 [CNSC2008b]) and the guidance document (GD-310 [CNSC2012b]).

> RD-310 identifies high-level regulatory information for a nuclear power plant licence applicant's preparation and presentation of a safety analysis. In particular, it establishes a more modern risk-informed approach to the categorization of accidents, one that considers a full spectrum of possible events, including the events of greatest consequence to the public. The CNSC expects proponents and applicants for new reactor licences to immediately apply this regulatory document in new-build submissions. In the context of existing reactors, CNSC expects the licensees to apply this document, in a graduated manner, to all relevant programs in future submissions.
>
> RD-310 explains the objectives of deterministic safety analysis, and in detail covers the requirements for safety analysis. In particular, it covers identification and classification of events following the international practice, i.e., groups them into Normal Operation (NO), Anticipated Operational Occurrences (AOOs), Design Basis Accidents (DBAs), and Beyond Design Basis Accidents (BDBAs), and explains the acceptance criteria. However, most of the details in the document are focussed on the safety analysis methods and assumptions, including methods, data, assumptions, computer code requirements, and required conservatisms in the analysis. The document also covers the required documentation that a licence applicant needs to prepare, and the time line for updating this documentation.

9.5.8 Reliability programs for NPPs: RD/GD-98

Regulatory document RD/GD-98, *Reliability Programs for Nuclear Power Plants* [CNSC2012a], sets out the requirements and guidance of the CNSC for the development and implementation of a reliability program for nuclear power plants in Canada. One of the important aspects of this document is to provide a clear definition of the Systems Important to Safety (SIS) and how these are treated and classified in NPP design.

9.5.9 Reporting requirements for operating nuclear power plants: S-99

The purposes of this Regulatory Standard [CNSC2003] are:

- To help the Canadian Nuclear Safety Commission collect the information that it needs to ensure that a nuclear power plant is operating safely and to verify that the licensee is complying with regulatory requirements;
- To help applicants for operating licences for nuclear power plants design programs for collecting and reporting information in accordance with regulatory requirements; and
- To facilitate CNSC evaluations of the appropriateness, completeness, and timeliness of information reported to the CNSC by operators of nuclear power plants.

This document is a key document for utilities that operate nuclear power plants because it states the requirements for reporting of operational issues. The document groups the requirements into two groups: reporting unscheduled events, and reporting scheduled events.

9.5.10 Pre-licensing review of a vendor's reactor design: GD-385

Guidance document GD-385, Pre-Licensing Review of a Vendor's Reactor Design [CNSC2012], describes the pre-licensing review process provided by the CNSC for assessing a vendor's design for a nuclear power plant or small reactor. The review considers the areas of design that relate to reactor safety, security and safeguards. For this topic, a licensee or licence applicant is not obliged to satisfy any provisions through regulations or licence conditions, and therefore no regulatory document (RD) accompanies this guidance document.

A pre-licensing review is an optional service provided by the CNSC. The objective of a pre-licensing review is to increase regulatory certainty while ensuring public safety. The review can be undertaken by a reactor vendor prior to an applicant's submission of a licence application to the CNSC and can provide early identification and resolution of potential regulatory or technical issues in the design, particularly those that could result in significant changes to the design or safety analysis.

This review does not certify a reactor design and does not involve the issuance of a licence under the Nuclear Safety and Control Act. It is not required as part of the licensing process for a new nuclear power plant or small reactor. The conclusions of a design review do not bind or otherwise influence decisions made by the Commission, with whom the authority resides to issue licences for nuclear power plants and small reactors. It is different in these respects from the U.S. Standard Design Certification.

9.5.11 Licence to construct a nuclear power plant: RD/GD-369

To request CNSC assessment of a request for a construction licence, a formal application must be submitted to the Canadian Nuclear Safety Commission (CNSC) along with appropriate documentation. This CNSC guidance identifies the information that should be submitted to support such an application.

RD/GD-369 [CNSC2012c] applies to applications for a licence to construct a water-cooled nuclear power plant. It does not presuppose or limit an applicant's intention to follow any particular kind of water-cooled reactor technology. This document follows the format of the IAEA Safety Guide No. GS-G-4.1, *Format and Content of the Safety Analysis Report for Nuclear Power Plants*, but is more specific to Canadian regulatory practice. In following these guidelines, an applicant must submit the appropriate information to demonstrate that it is qualified and will make adequate and reasonable provisions to undertake the activity to be licensed, pursuant to sub-section 24(4) of the *Nuclear Safety and Control Act* and associated regulations.

RD/GD-369 is a combined document that lists and explains the requirements, but also provides guidance on how to address them. The document covers plant description; management of safety; site evaluation; general design aspects and support programs; design of plant structures, systems, and components; safety analysis; construction and commissioning; operational aspects; operational limits and conditions; radiation protection; environmental protection; emergency preparedness; radioactive and hazardous waste management; decommissioning and end-of life-aspects; and safeguards.

9.5.12 Severe accident management programs for nuclear reactors: G-306

The CNSC Guide on *Severe Accident Management Programs for Nuclear Reactors* [CNSC2006] describes a typical severe accident management (SAM) program for a nuclear reactor. A person who applies for, or holds, a licence to construct or operate a nuclear reactor can use this guide when developing and implementing measures to help:

a) Prevent the escalation of a reactor accident into an event involving severe damage to the reactor core;
b) Mitigate the consequences of an accident involving severe damage to the reactor core; and
c) Achieve a safe, stable state of the reactor and plant over the long term.

Some severe accidents (in particular dual failures, see Chapter 13) have historically been part of the CANDU design basis. However the spectrum of severe accidents that must be evaluated has broadened in the past few decades due to the maturation of probabilistic safety assessment as an evaluation tool and to the real events at Three Mile Island, Chernobyl, and Fukushima. Because operating plants may not have been explicitly designed against extreme events, in the past, severe accident assessment and management looked at the capabilities of existing plant systems to mitigate such events and developed severe-accident management procedures to take advantage of these capabilities. However, especially post-Fukushima, design measures (retrofits) are being implemented specifically to mitigate a spectrum of severe accidents, for example, filtered containment venting.

A Severe Accident Management (SAM) program provides an additional defence against the consequences of those accidents that fall beyond the scope of events considered in the reactor design basis. The establishment of a SAM program should ensure that personnel involved in managing an accident have the information, procedures, and resources necessary to carry out effective on-site actions.

G-306 provides guidance on the goals and principles of severe-accident management, considerations for program development (risk assessment and accident analysis), determination of high-level accident response (preventive and mitigating actions, evaluation of systems and equipment, and assessment of material resources), and SAM procedures and guidelines.

9.5.13 Containment systems for CANDU nuclear power plants: R-7

This regulatory document [CNSC1991] is one of the original series of AECB documents. It was superseded by RD-337, except in areas in which it is consistent with RD-337, but provides more information.

The document describes the design, operating, and testing requirements for the containment system. It includes definition of the containment envelope, dose limits under accident conditions (see Section 9.5.17), structural integrity, leakage criteria, and requirements in several important areas, such as availability, environmental qualification, shielding, status monitoring, and seismic provisions.

9.5.14 Shutdown systems for CANDU nuclear power plants: R-8

This regulatory document [CNSC1991a] is one of the original series of AECB documents. It was superseded by RD-337 except in areas in which it is consistent with RD-337, but provides more information.

The document describes the design, operating, and testing requirements for the shutdown systems. It includes definition of the minimum allowable performance standards and requirements in several important areas, such as performance, environmental qualification, availability, separation and independence, actuation instrumentation, status monitoring, and seismic provisions.

9.5.15 Emergency core cooling systems for CANDU nuclear power plants: R-9

This regulatory document [CNSC1991b] is one of the original series of AECB documents. It was superseded by RD-337, except in areas in which it is consistent with RD-337, but provides more information.

The document describes the design, operating, and testing requirements for the emergency core cooling system. It includes definition of the minimum allowable performance standards and requirements in several important areas, such as core cooling, environmental qualification, availability, separation and independence, actuation instrumentation, leakage control, inadvertent operation, shielding, status monitoring, and seismic provisions.

9.5.16 Use of two shutdown systems in reactors: R-10

This regulatory document [CNSC1991b] is one of the original series of AECB documents. It was superseded by RD-337.

The document formalized the requirement for two independent shutdown systems:

"All nuclear power reactors licensed for construction in Canada after January 1, 1977, shall incorporate two independent protective shutdown systems unless otherwise approved by the Board."

It required that the two shutdown systems be independent, reliable, diverse, and individually capable of meeting regulatory dose limits[13]. Therefore, it could be assumed that at least one system would operate as designed when required (i.e., there was no need to postulate simultaneous unavailability of both systems after an accident).

9.5.17 Classification of systems, design basis accidents, and dose limits

The selection and classification of accidents for safety analysis, or in other words the definition of design basis accidents, is covered extensively in Chapter 13 and is summarized here only for convenience:

The deterministic safety analysis limits under which all large operating CANDU plants up to but excluding Darlington have been licensed can be found in [Hurst1972]. The spectrum of possible design basis accidents was collapsed into two broad categories: *single failures*, or the failure of any one process *system* in the plant, and *dual failures*, a much less likely event defined as a single failure coupled with the unavailability of either a shutdown system, or containment, or the emergency core cooling system, these constituting the so-called *special safety systems*. For each category, a frequency and a consequence limit was chosen that had to be satisfied. In addition, to deal with the siting of a reactor (Pickering A) next to a major population centre (Toronto), population dose limits were defined for each category of accident.

The limits were as follows (sometimes this is called the Siting Guide):

Table 3 Single / dual failure dose limits

Accident	Maximum Frequency	Individual Dose Limit	Population Dose Limit
Single Failure	1 per 3 years	0.005 Sv	10^2 Sv
		0.03 Sv thyroid	10^2 Sv thyroid
Dual Failure	1 per 3000 years	0.25 Sv	10^4 Sv
		2.5 Sv thyroid	10^4 Sv thyroid

For the licensing of Darlington, as discussed in Chapter 13, Consultative Document C-6 was used. This expanded the number of accident classes to five, as follows:

13 This is an oversimplification of R-10. R-10 actually specifies that for single failures, “at least” one shutdown system had to meet dose limits, whereas for dual failures, each shutdown system had to be individually capable of so doing. The distinction was removed in later practice, so that each shutdown system alone had to meet requirements for all design basis accidents.

Table 4 Consultative document C-6 dose limits

Event Class	Expected Frequency per reactor-y [Charak, 1995][14]	Whole-Body Dose (Sv)	Thyroid Dose (Sv)
1	$> 10^{-2}$	0.0005	0.005
2	10^{-2} to 10^{-3}	0.005	0.05
3	10^{-3} to 10^{-4}	0.03	0.3
4	10^{-4} to 10^{-5}	0.1	1
5	$< 10^{-5}$	0.25	2.5

Finally, for new plants (and as an evaluation tool for existing plants), a classification scheme based more on international practice has been used (from [CNSC2008] and [CNSC2008b]):

Table 5 New plants in Canada: dose limits

Event	Frequency	Dose Limit (Sv)
Anticipated Operational Occurrence	$\geq 10^{-2}$ / reactor-year	0.0005
Design Basis Accident	10^{-2} to 10^{-5} / reactor-year	0.020

Plant licences refer to the Final Safety Analysis Report, which in turn references the appropriate classification scheme.

9.6 CNSC Staff Review Procedures

CNSC staff have prepared a set of Staff Review Procedures (SRPs) used during the technical assessment stage of the environmental assessment and site licensing process. They provide instructions to CNSC staff on the conduct of an assessment. They also inform potential applicants and the public about the criteria used to assess environmental impact statements and licence applications for new nuclear power plants. SRPs are not regulatory documents. They are available on the CNSC Web site. Other SRPs are under development.

9.7 CNSC CANDU Safety Issues

All regulators track safety-related issues which are not so pressing as to require immediate regulatory action, but have not been addressed convincingly enough by the operator. Typically, these include knowledge gaps, safety analysis assumptions, and methodologies. Such issues in Canada were formerly called “Generic Action Items” (GAIs); these have now been phased out as a regulatory tool and replaced by the CANDU Safety Issues. Generally, they pertain to more than one operating plant.

14 Expected frequency ranges are not part of C-6; they were used by Ontario Hydro in the licensing of Darlington to classify events not listed in C-6.

The list of CANDU Safety Issues was developed from:

- The IAEA document, Generic Safety Issues for Nuclear Power Plants with Pressurized Heavy Water Reactors and Measures for their Resolution [IAEA2007a];
- Regulatory oversight of currently operating reactors;
- Results of life-extension assessments;
- Safety issues identified in pre-licensing reviews of new CANDU designs.

They are classified into three categories:

- Category 1 means issues that have been satisfactorily addressed in Canada;
- Category 2 identifies issues that are a concern in Canada, but have appropriate measures in place to maintain safety margins;
- Category 3 issues are a concern in Canada and measures are in place to maintain safety margins, but the adequacy of these measures needs to be confirmed.

For the last, the industry and the CNSC have used a risk-informed decision-making (RIDM) process to identify, estimate, and evaluate the risks associated with each and to recommend measures to control these risks. None of these issues has yielded a risk significance level that required immediate corrective action.

As of August 2013 [GovCan2013a], there are 16 Category 3 issues outstanding, including six associated with large-break loss-of-coolant accidents (LBLOCA) and ten other safety issues not associated with LBLOCA.

The current status of each CANDU Safety Issue is reported publicly at International Nuclear Safety Convention meetings [GovCan2013a].

9.8 CNSC Fukushima Action Items

On March 11, 2011, a magnitude 9.0 earthquake, followed by a devastating tsunami, struck Japan. The combined impact of the earthquake and tsunami on the Fukushima Dai-ichi nuclear power plant caused a severe nuclear accident. Details are presented in Chapter 13.

The CNSC established the CNSC Fukushima Task Force to evaluate the operational, technical, and regulatory implications for CANDU nuclear power plants and the capability of CANDU NPPs to withstand conditions similar to those that triggered the Fukushima accident. It issued its recommendations in the Fukushima Task Force Report [CNSC2011]. In response, the CNSC Staff developed an Action Plan [CNSC2011a], which mandates actions both for the utilities and for the CNSC itself. In these documents, CNSC staff requested utilities to conduct certain activities in the following areas:

a) Safety-review criteria, including identification and magnitudes of external events, adequacy of design-basis-accident analysis, consideration of beyond-design-basis accidents, implementation of severe-accident management, licensees' emergency response plans, nuclear emergency management in Canada, and CNSC regulatory frameworks and processes;
b) Strengthening reactor defence-in-depth;
c) Enhancing emergency response; and
d) Improving regulatory framework and licensing.

This work resulted in a number of Fukushima Action Items that the Canadian industry is putting in place.

9.9 Canadian Codes and Standards

The Canadian Standards Association (CSA) is a not-for-profit membership-based association serving business, industry, government, and consumers in Canada and the global marketplace. CSA develops standards that enhance public safety and health, advance the quality of life, and help to preserve the environment.

The objective of the CSA Nuclear Standards Program is to help promote a safe and reliable nuclear power industry in Canada and to have a positive influence on the international nuclear power industry. Although focussing on nuclear power plants, the program provides guidance for other types of nuclear facilities on selected topics such as radioactive waste management and environmental releases. Compliance with CSA nuclear standards is mandatory for those that are referenced in a plant licence and is *de facto* mandatory for other organizations which contribute to design, analysis, and other aspects of plant construction and operation. Table 6 shows selected CSA Standards relevant to nuclear power plants.

Table 6 Selected key CSA codes and standards

Document number	Title	Creation / Revision or Reaffirmed date
CSA N285.0	General Requirements for Pressure-Retaining Systems and Components in CANDU Nuclear Power Plants/Material Standards for Reactor Components for CANDU Nuclear Power Plants	2008
CSA N285.4	Periodic Inspection of CANDU Nuclear Power Plant Components	2009
CSA N285.5-13	Periodic Inspection of CANDU Nuclear Power Plant Containment Components	1998 (2013)
CSA N285.8	Technical Requirements for In-Service Evaluation of Zirconium Alloy Pressure Tubes in CANDU Reactors	2010
CSA N286-05	Management System Requirements for Nuclear Power Plants	2005 (2010)
CSA N286.7	Quality Assurance of Analytical, Scientific, and Design Computer Programs for Nuclear Power Plants	1999 (2007)
CSA N287.1	General Requirements for Concrete Containment Structures for CANDU Nuclear Power Plants	July 1993 (2009)
CSA N287.7-08 (R2013)	In-Service Examination and Testing Requirements for Concrete Containment Structures for CANDU Nuclear Power Plants	2008 (2013)
CSA N288.4-10	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	2010 (1990)
CSA N288.5-11	Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	2011
CSA N288.6-12	Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills	2012
CSA N288.1	Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities	2008
CSA N289.1	General Requirements for Seismic Qualification of CANDU Nuclear Power Plants	2008

Document number	Title	Creation / Revision or Reaffirmed date
CSA N290.1	Requirements for the Shutdown Systems of CANDU Nuclear Power Plants	1980 (2006)
CSA N290.15-10	Requirements for the Safe Operating Envelope of Nuclear Power Plants	2010
CSA N291	Requirements for Safety-Related Structures for CANDU Nuclear Power Plants	2008
CSA N293	Fire Protection for CANDU Nuclear Power Plants	2007
CSA N294	Decommissioning of Facilities Containing Nuclear Substances	2009

10 Reactor Licensing Process in Canada[15]

CNSC material has been used throughout this section and referred to in specific documents where appropriate. *Italic* fonts have been used to indicate where statements from CNSC documents have been used essentially verbatim.

This section covers the licensing process of both new-build NPPs and operating reactors. The emphasis is on new-build NPPs. However, certain aspects of the licensing (relicensing) of operating reactors are also covered. See [CNSC2008a] and [Andrews2012].

The focus is on the Canadian licensing process, but relevant and important aspects of, and differences from, the licensing process in other countries are also covered at a high level.

10.1 Licensing Process

Nuclear power plants are defined as Class I nuclear facilities, and the regulatory requirements for these facilities are found in the *Class I Nuclear Facilities Regulations*. The regulations also require separate licences for each of the five phases in the lifecycle of a nuclear power plant:

i. licence to prepare a site, including the environmental assessment;
ii. licence to construct;
iii. licence to operate;
iv. licence to decommission; and
v. licence to abandon.

There are four major steps in the licensing process:

1. Applicant submits a licence application
2. Environmental assessment

15 Some of the descriptive material has been drawn from the Web site of the CNSC.

3. Licensing technical assessment
4. CNSC renders its decision.

We summarize these in turn.

10.1.1 Licence application

In Canada, the licensing process begins when an application is received by CNSC. All new licence applications or amendments to existing licences require the approval of the Commission or a CNSC Designated Officer. The Commission is notified when an application that requires a decision from them has been filed.

The preparation of a licence application needs to consider all regulatory criteria as defined by the *Nuclear Safety and Control Act*, and *relevant regulations,* CNSC requirements and expectations, international and domestic standards, and applicable international obligations.

For major resource projects such as nuclear power plants, uranium mines, or fuel processing facilities, a project description is sent to Natural Resources Canada's Major Projects Management Office (MPMO). MPMO is responsible for coordinating the work of all the federal departments and agencies that have a role to play in the regulatory process for major resource projects. MPMO offers licensees a single entry point into the federal regulatory system.

For new nuclear power plants in Canada, three licences are initially required:

1. licence to prepare site, including an environmental assessment
2. licence to construct the nuclear power plant, and
3. licence to operate.

The regulatory process in Canada in principle makes it possible to combine these processes, but the normal route is for an applicant to request them sequentially, i.e., each process is completed when the appropriate licence is issued.

Very often, before a formal licensing process is initiated through an application by the NPP owner or operator, a pre-licensing process is performed by the NPP design organization, as explained in detail in Section 5.

The key element of a successful licensing process is to prepare adequate documentation that meets regulatory requirements and expectations. Figure 14 provides a general idea of the level of detail required during different phases of the licensing process. On the left-hand side, the reactor design process is shown, and on the right-hand side, the level of documentation completeness. From top to bottom, the design and documentation move from the initial stage to completeness. The middle of the diagram provides an indication of the percentage completeness of the design. However, the design and documentation completeness level is discussed and agreed in detail with CNSC at the beginning of a licensing process.

The technology vendor must complete a conceptual design and appropriate documentation before engaging in any licensing activity. After the conceptual design has been firmed up, which means that key design options and characteristics have been decided, a basic engineering program begins to develop a preliminary design. During the basic engineering process, at some point, the technology vendor may decide to engage the regulator in performing a non-binding pre-licensing review. This is not a mandatory process, and technology vendors may or may not decide to request it.

As shown in Figure 14, from [CNSC2012], following the preliminary design, detailed design is conducted. After the detailed design and appropriate documentation have been prepared, the licensee applies for a construction licence. During the regulatory review for the construction licence, further detailed design activities related to the construction phase may be conducted. After the regulatory body issues an operating licence, the licensee will continue to provide ongoing design support activities.

Section 13 gives as an example the information that must be submitted in Canada for construction and operating licences.

At any time during operation, if a design or procedural change is considered for implementation which deviates from the safety case or from any prior licence issued by CNSC, an approval process for the particular change must be conducted and CNSC approval obtained before implementing the change.

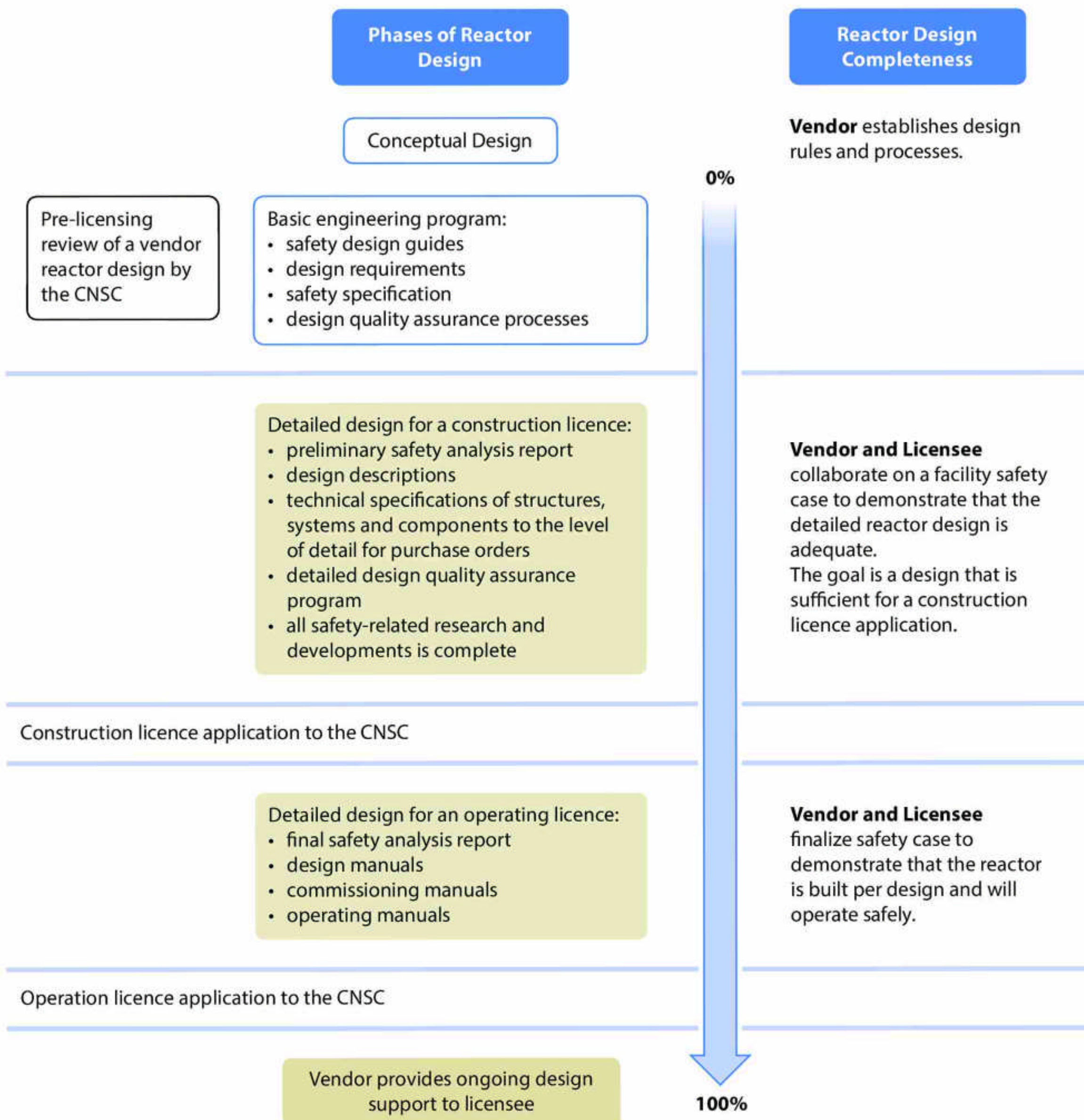

Figure 14 Design and documentation completeness phases

10.1.2 Environmental assessment

CNSC has obligations and responsibilities under the *Canadian Environmental Assessment Act* (CEAA), which is the basis for federal Environmental Assessments in Canada. See [CEAA2012].

During the application review process, CNSC determines whether an environmental assessment (EA) is required for a proposed project. EAs are used to predict the potential environmental effects of a specific project and to determine whether these effects should be mitigated, and by what means, before a project is carried out. EAs consider environmental components such as:

- air, water, and soil quality;
- noise;
- human health;
- aboriginal interest, physical and cultural heritage; and
- use of land and resources.

EAs provide opportunities for public participation in activities undertaken by the potential licensees, the CNSC, or both, including aboriginal consultations.

Under the CEAA [GovCan2012], there are two levels of environmental assessment: a standard environmental assessment and a panel review. The standard environmental assessment is the default level of assessment applicable to a designated project; the second, higher level of environmental assessment is a panel review. The CEAA imposes time limits for environmental assessments. Most standard environmental assessments must be completed within one year, while panel reviews are limited to two years.

At the beginning of an environmental assessment, CNSC provides project-specific advice and guidance about what should be assessed, such as the scope of the project and the factors that apply to each individual project. Further guidance is available from CNSC for conducting these technical studies.

All applications for new nuclear facilities and some amendments to existing licences require the applicant to undertake an EA and technical studies. After technical studies are completed, the applicant can submit an Environmental Impact Statement (EIS) to CNSC, who will assess the EIS and prepare an EA Report. For major new facilities, the assessment of an applicant's EIS, referred to as an EA technical assessment, and is guided by an Assessment Plan and EIS-related *Staff Review Procedures*. The EA report contains recommendations for an EA decision, including all appropriate mitigation measures and the requirements of a follow-up program. Pursuant to the CEAA, the Responsible Authority (the Commission or a delegated officer) must make its EA decision before any licensing action can be considered for the project.

Only one EA is required for a project, even if that project requires separate licences for different phases (i.e., licence to prepare site, licence to construct, etc.). However, additional EAs may be required if a project changes over time. For a new nuclear power plant, if construction is to be performed at a new site, the EA is conducted before a site licence is issued. For a new nuclear power plant where construction is intended on a site that already has other NPP units, the EA is conducted before site preparation can begin for the new NPP addition.

10.1.3 Licensing technical assessment

After receipt of a licence application, CNSC staff undertakes a variety of technical assessments according to a prescribed Assessment Plan and licensing-related Staff Review Procedures to ensure that each application complies with its corresponding regulatory requirements. Peer reviews are sometimes used, when additional rigour is required.

The Licensing Technical Assessment considers all regulatory criteria as defined by the Nuclear Safety and Control Act, relevant regulations, CNSC requirements and expectations, international and domestic standards, and applicable international obligations.

At the end of this process, CNSC staff make a recommendation for a decision on the licence application through an integrated assessment report. A recommended compliance plan for each licence is also developed, and the mitigation measures included in the follow-up program, if applicable, are included in the licence.

10.1.4 CNSC decision

The final decision on a licence is made by either the Commission (e.g., for licences for nuclear power plants) or a CNSC designated officer.

When the decision is to be made by the Commission, public hearings may be held to take into account the views, concerns, and opinions of interested parties, including the applicant and interveners. This is an important part of the process of establishing regulatory policy, making licensing decisions, and implementing programs. CNSC staff recommendations are presented, and the applicant and the public are normally given a chance to make statements.

Most decisions involving major nuclear facilities are made through a two-session[16] public hearing process. The first hearing is for presentations by the applicant and CNSC staff, and the second for intervener presentations. Commission members may ask questions in both cases. The applicant and CNSC staff also attend the second hearing and respond to further questioning by the Commission.

Whether made by the Commission or a CNSC designated officer, the decision will take the form of the granting of a licence or certificate, or else a letter of refusal.

The next section provides more information about the EA process for NPP construction on a new site.

10.2 Site Selection and Site Licensing

This section covers the criteria used for appropriate site selection. A number of regulatory documents in Canada and internationally cover this topic, e.g., [CNSC2008c].

The CNSC must be satisfied that it is feasible to perform the site preparation activities in a manner that will satisfy all health, safety, security, and environmental protection requirements. In addition, the Commission cannot issue a site preparation licence unless a decision as a result of the EA has been made, indicating that the project may proceed; however, these approval

16 The first hearing is known as “Day 1” and the second as “Day 2”, although they may last more than one day each.

processes may proceed in parallel.

The following aspects are considered when evaluating the suitability of a site over the life of a nuclear power plant:

- the potential effects of external events (such as seismic events and floods) and human activity on the site;
- the characteristics of the site and its environment which could influence the pathways of radioactive and hazardous material that may be released; and
- the population density, population distribution, and other characteristics of the region, insofar as they may affect the implementation of emergency measures and the evaluation of risks to individuals, the surrounding population, and the environment.

Under the regulations, an applicant must submit, for any licence, a Project Description of the facility and plans showing the location, perimeter, areas, structures and systems of the facility. An application for a Licence to Prepare Site does not require detailed information or determination of a reactor design; however, high-level design information is required for the environmental assessment that precedes the licensing decision for a Licence to Prepare Site. An application for a Licence to Construct must contain more detailed information about the reactor design and a supporting safety case.

The goal of the CNSC, during the site preparation stage, is to ensure that the site characteristics which may have an impact on health, safety, security, and the environment have been identified, and that these characteristics can and will be taken into consideration in the design, operation, and decommissioning of the proposed nuclear power plant. The technical information arising from the consideration of external events, site-specific characteristics, and supporting assessments is used as input into the design of the nuclear power plant and must be included in the application.

The Canadian Environment Assessment Act, as amended in 2012 [GovCan2012], gives the CNSC decision-making authority on all environmental assessments (EAs) for nuclear projects. Therefore, both environmental assessment and site licensing processes occur concurrently under the authority of the CNSC Commission. This ensures that the information submitted by the proponent can be considered by public and government agencies through a single process and that any appropriate decisions under EA and site licensing can be made by a single body—the CNSC Commission. The Commission process establishes the level of an environmental assessment based on risk and other factors; for example, an application for a site for a new nuclear power plant will almost certainly require a panel review.

The CNSC Commission makes a decision on the EA within the 24-month timeline established for site licensing.

10.3 Construction Licence

During this stage, CNSC undertakes a variety of technical assessments according to a prescribed assessment plan and licensing-related staff review procedures to ensure that each application complies with its corresponding regulatory requirements. The scope and duration of each assessment will vary depending on the type of licence requested. Peer reviews are sometimes used when additional rigour is required.

The licensing technical assessment considers all regulatory criteria as defined by the Nuclear

Safety and Control Act, relevant regulations, CNSC requirements and expectations, international and domestic standards, and applicable international obligations.

The CNSC reviews the submitted application and judges whether the information contained in the application is acceptable and whether the licence applicant is qualified and will make adequate provision for safety, etc., in carrying out the licensed activity (in accordance with 24(4) of the NSCA). If the CNSC accepts this information, it becomes the reference safety case for the plant and will form part of the licensing basis at the construction licence stage. The information provided with the licence application, including the documents to which the application makes reference, constitutes the construction safety case. The requirements for the safety case are listed in detail in [CNSC2012c].

The information required in support of the application to construct a nuclear power plant includes, for example:

- a description of the proposed design for the nuclear power plant, taking into consideration the physical and environmental characteristics of the site;
- environmental baseline data on the site and surrounding area;
- a preliminary safety analysis report showing the adequacy of the design;
- measures to mitigate the effects on the environment and the health and safety of persons that may arise from construction, operation, or decommissioning of the facility;
- information on potential releases of nuclear substances and hazardous materials and proposed measures to control them;
- programs and schedules for recruiting and training operations and maintenance staff;
- and in general, those safety control areas listed in Section 9.5.2.

After the construction licence application has been received, the CNSC performs a comprehensive assessment of the design documentation, the preliminary safety analysis report, the construction program, and any other information required by the regulations. The assessment focusses on determining whether the proposed design and safety analysis, along with other required information, meet regulatory requirements.

Specifically, the evaluation involves rigorous engineering, scientific analysis, and engineering judgment, taking into consideration the CNSC's experience and knowledge of the best practices in nuclear plant design and operation, as gained from existing power plants in Canada and around the world. This review may take place in parallel with the Environmental Assessment and site preparation licensing process. At the end of this process, CNSC staff makes a recommendation for a decision on the licence application, through an integrated assessment report. Occasionally, the recommendations include proposed changes to the regulatory framework to accommodate evolving nuclear technologies. A recommended compliance plan for each licence is also developed, and the mitigation measures included in the follow-up program, if applicable, are included in the licence.

In addition to reviewing the information included in the application, the CNSC also verifies that any outstanding issues from the site preparation stage have been resolved. The CNSC staff's conclusions and recommendations from these reviews are documented in reports submitted to the Commission; the Commission then makes the final decision on the issuance of the construction licence. As noted earlier, the Commission will not issue a licence unless it is satisfied that the applicant will make adequate provisions to protect health, safety, security and the environment, and to respect the international obligations to which Canada has agreed. As such, it is the responsibility of the applicant to show that there are no major safety issues outstanding at the time the Commission considers the application for a construction licence.

During the construction phase, the CNSC carries out compliance activities to verify that the licensee is complying with the NSCA, with associated regulations, and with its licence. Such compliance activities focus on confirming that plant construction is consistent with the design, that the licensee is demonstrating adequate project oversight and confirming that quality assurance requirements are met, and that the licensee is respecting any requirements of the EA follow-up program.

In the latter part of construction, regulatory attention turns towards the inactive commissioning program (without fuel loaded) and associated activities, whose purpose is to demonstrate to the extent practicable that all systems, structures, and components function in accordance with their design specifications.

10.4 Operating Licence

When applying for a Licence to Operate a nuclear power plant, it is the responsibility of the applicant to demonstrate to the CNSC that it has established the safety management systems, plans, and programs that are appropriate to ensure safe and secure operation. Information required by the CNSC in support of the application for a licence to operate includes, for example:

- a description of the structures, systems, and equipment at the nuclear power plant, including their design and operating conditions;
- the final safety analysis report; and
- proposed measures, policies, methods, and procedures for:
  - commissioning systems and equipment;
  - operating and maintaining the nuclear facility;
  - handling nuclear substances and hazardous materials;
  - controlling the release of nuclear substances and hazardous materials into the environment;
  - preventing and mitigating the effects on the environment and on health and safety resulting from the operation and subsequent decommissioning of the plant;
  - assisting off-site authorities in emergency preparedness activities, including assistance to deal with an accidental off-site release; and
  - nuclear security.

A typical application [OPG2013] would also cover:

- Management system, including safety culture;
- Human performance management;
- Operating performance and corrective action program;
- Fitness for service;
- Probabilistic safety analysis;

- Radiation protection;
- Conventional health and safety;
- Emergency management and fire protection;
- Waste management;
- Safeguards;
- Packaging and transport;
- Community relations and public information;
- Financial guarantees;
- Nuclear liability insurance;
- Open action items.

In addition to assessing the information included in the application to operate the nuclear power plant, the CNSC also verifies that any outstanding issues from the construction licensing stage have been resolved.

The CNSC staff's conclusions and recommendations from these reviews are documented in reports submitted to the Commission, which then makes the final decision on issuance of the operating licence.

The Licence to Operate will enable the operator to begin active commissioning. The purpose of the commissioning activities is to demonstrate that the plant has been constructed in accordance with the design and that the systems, structures, and components important to safety are functioning in accordance with their design specifications. The initial operating licence is typically issued with conditions (hold points) to load nuclear fuel, permit reactor start-up, and operation at power in steps up to the design rating of the plant. All the relevant commissioning tests must be satisfactorily completed before the hold points can be released.

During the subsequent long-term operation of the plant, the CNSC carries out compliance activities in order to verify that the licensee is complying with the NSCA, associated regulations, and its licence terms. If the compliance activities identify any non-compliance or adverse trend, there is a range of possible actions that the CNSC can take, from a request for licensee action to prosecutions.

10.4.1 Ongoing oversight

Operating NPPs are subject to ongoing regulatory monitoring, screening, and inspections. Canadian CANDU plants have resident full-time CNSC inspectors on-site to provide immediate interaction with the operator and to view the station and equipment first-hand.

Aspects of continuing CNSC oversight include:

- Informal information exchange;
- Attending industry working groups as observers;
- Periodic formal audits and inspections of plant operation and management;
- Planned routine assessments and evaluations;
- Reactive inspections following events;
- Formal correspondence;
- Monitoring of progress on CANDU Safety Issues and on specific station action items;
- Conducting an annual review of the safety performance of NPPs;
- Revision to the Licence Condition Handbooks;

- Enforcement actions;
- Orders (legal instruments);
- Licence amendments initiated by CNSC staff;
- Licence amendments or renewals initiated by licensees; and
- Commission meetings and hearings.

10.4.2 Operating licence renewal and refurbishment

There are two longer-term activities which provide an opportunity to ensure that a plant continues to meet regulatory requirements.

Operating licences are typically renewed about every five years in Canada. This requires a review, update, and resubmission of the safety case to reflect changes in plant design and to assess the plant against evolving regulatory requirements. The status of Action Items, CANDU Safety issues, station-specific items, station safety performance, operating experience, quality assurance, and other items are all reviewed at the time of renewal of an operating licence.

CANDU plants can be refurbished by replacement of the fuel channels, typically after about 25 years of operation. This action triggers a much more extensive comparison of the plant against modern standards, as described in Section 9.5.6.

10.5 Licence to Decommission and Return Site to Green Site

At the end of a nuclear power plant's useful life, it will be necessary to decommission the facility. This will require a separate licence from the Commission. Information on decommissioning plans and financial guarantees will, in practice, have been taken into account at all stages of licensing (site preparation, construction, and operation) [CNSC2008a]. Factors taken into account when evaluating an application to decommission a nuclear power plant include, but are not limited to:

- the major components and systems within the facility, which must be properly considered during decommissioning planning;
- the design features that will facilitate decommissioning activities and reduce the spread of contamination during operation;
- the expected levels of activation and contamination within the facility following the end of operation;
- an assessment of structures to ensure that they are capable of being maintained for the proposed period of storage and monitoring;
- the disposal of some of the nuclear materials and radiation devices (e.g., fresh fuel, spent fuel, heavy water, water contaminated with tritium, and other prescribed nuclear materials); and
- the quantities or volumes of wastes of all types (radioactive and hazardous) expected during decommissioning activities.

In addition, the licensees must show that they have sufficient funds to decommission the plant, provide for the long-term management of spent nuclear fuel, and provide continuing environmental monitoring and maintenance of the site for the duration of the licence.

11 Problems

1. Tokai-Mura, 1999: Locate the following material: International Atomic Energy Agency, Report on the Preliminary Fact Finding Mission Following the Accident at the Nuclear Fuel Processing Facility in Tokaimura, Japan; IAEA report, 1999. You may also find or use other documents as well. Assess the accident in terms of regulatory effectiveness, using some of the ideas in this chapter. Propose lessons learned. Which aspects of regulatory performance were also apparent after the Fukushima accident?

2. Compare the approaches taken by the USNRC and the CNSC with respect to large Loss of Coolant Accident (LOCA) regulatory acceptance criteria.

   a. Find out what the acceptance criteria are and where they are documented. Note: not all Canadian criteria are set by the CNSC; you may have to look at CANDU safety reports.

   b. Both Canadian and U.S. practices set limits on sheath oxidation in a LOCA to prevent embrittlement on rewet by Emergency Core Cooling (ECC). Compare the two criteria and explain the rationale in each case.

   c. Find the requirements on shutdown systems for both the United States and Canada. What is the typical reliability of the shutdown system in each case? How are postulated impairments of the shutdown system handled in each case?

3. Review the U.S. General Design Criteria (GDC) in 10CFR, Appendix A to part 50. Which design criteria (if any) would be *intrinsically* difficult for CANDU to meet? If you find any such criteria, what is the safety concern that these GDCs address, and how is that concern addressed in CANDU design?

4. Locate the U.K. Safety Assessment Principles issued by HSE. Compare and contrast the requirements for safety systems with those in CNSC document RD-337. Which ideas are common? Which are different? (Compare the underlying requirement, not the exact wording).

12 Appendix A—Examples of U.K. Safety Assessment Principles

This Appendix lists some examples of U.K. Safety Assessment Principles which illustrate the non-prescriptive technology-neutral approach. The text of the SAP is in **bold** and the commentary in normal typeface.

===

"Engineering principles: design for reliability Single failure criterion EDR.4

During any normally permissible state of plant availability no single random failure, assumed to occur anywhere within the systems provided to secure a safety function, should prevent the performance of that safety function.

175 Consequential failures resulting from the assumed single failure should be considered as an integral part of the single failure. Further discussion of the single-failure criterion is given in IAEA Safety Standard NS-G-1.2"

===

"Engineering principles: safety systems: Diversity in the detection of fault sequences ESS.7

The protection system should employ diversity in the detection of fault sequences, preferably by the use of different variables, and in the initiation of the safety system action to terminate the sequences.

342 This principle applies in particular to U.K. civil nuclear power reactor safety systems and in particular to high-integrity safety systems."

===

"Engineering principles: reactor core Shutdown systems ERC.2

At least two diverse systems should be provided for shutting down a civil reactor.

444 Where a shutdown system is also used for the control of reactivity, a suitable and sufficient shutdown margin should be maintained at all times.

445 Reactor shutdown and subsequent hold-down should not be inhibited by mechanical failure, distortion, erosion, corrosion, etc., of plant components, or by the physical behaviour of the reactor coolant, under normal operation or design basis fault conditions."

===

This last SAP was part of the basis for fitting a second shutdown mechanism (large-volume boron injection tanks) to the Sizewell-B PWR.

13 Appendix B—Information Required in Licence Applications

(Construction and Operating Licences in Canada, as Examples)

From [GovCan2012a]

Licence to Construct

An application for a licence to construct a Class I nuclear facility shall contain the following information in addition to the information required by section 3:

(a) a description of the proposed design of the nuclear facility, including the manner in which the physical and environmental characteristics of the site are taken into account in the design;

(b) a description of the environmental baseline characteristics of the site and the surrounding area;

(c) the proposed construction program, including its schedule;

(d) a description of the structures proposed to be built as part of the nuclear facility, including their design and their design characteristics;

(e) a description of the systems and equipment proposed to be installed at the nuclear facility, including their design and their design operating conditions;

(f) a preliminary safety analysis report demonstrating the adequacy of the design of the nuclear facility;

(g) the proposed quality assurance program for the design of the nuclear facility;

(h) the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement;

(i) the effects on the environment and the health and safety of persons that may result from the construction, operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;

(j) the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;

(k) the proposed measures to control releases of nuclear substances and hazardous substances into the environment;

(l) the proposed program and schedule for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility; and

(m) a description of any proposed full-scope training simulator for the nuclear facility.

Licence to Operate

An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3:

(a) a description of the structures at the nuclear facility, including their design and their design operating conditions;
(b) a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;
(c) a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;
(d) the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility;
(e) the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances;
(f) the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement;
(g) the proposed commissioning program for the systems and equipment that will be used at the nuclear facility;
(h) the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;
(i) the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;
(j) the proposed measures to control releases of nuclear substances and hazardous substances into the environment;
(k) the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of security, including measures to
(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release,
(ii) notify off-site authorities of an accidental release or the imminence of an accidental release,
(iii) report information to off-site authorities during and after an accidental release,
(iv) assist off-site authorities in dealing with the effects of an accidental release, and
(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release;
(l) the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts;
(m) the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and
(n) the results that have been achieved in implementing the program for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility.

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15 Glossary

ACNS	Advisory Committee on Nuclear Safety (Canada, historical)
ACRS	Advisory Committee on Reactor Safeguards (USA)
AEC	Atomic Energy Commission (USA)
AECA	Atomic Energy Control Act (Canada)
AECB	Atomic Energy Control Board (Canada)
ALARA	As Low as Reasonably Achievable
ALARP	As Low as Reasonably Practical (UK)
ASLB	Atomic Safety and Licensing Board (USA)
BDBA	Beyond Design Basis Accident
BSL	Basic Safety Limit (UK)
BSO	Basic Safety Objective (UK)
BWR	Boiling Water Reactor
CEAA	Canadian Environmental Assessment Act
CFR	Code of Federal Regulations (USA)
CNSC	Canadian Nuclear Safety Commission
C/S	Containment and Surveillance
CSA	Canadian Standards Association
DBA	Design Basis Accident
DIV	Design Information Verification
EA	Environment Agency (UK)
EA	Environmental Assessment (Canada)
ECC	Emergency Core Cooling
EIS	Environmental Impact Statement
ENSREG	European Nuclear Safety Regulators Group
EU	European Union
GAR	Global Assessment Report
GDA	Generic Design Assessment (UK)
GDC	General Design Criteria (US)
GAI	Generic Action Item

HSE	Health and Safety Executive (UK)
IIP	Integrated Implementation Plan
IAEA	International Atomic Energy Agency
INPO	Institute of Nuclear Power Operations
INSAG	International Safety Advisory Group (IAEA)
IRRS	Integrated Regulatory Review Service (IAEA)
LBLOCA	Large Break Loss of Coolant Accident
LNT	Linear No Threshold (dose response hypothesis)
LOCA	Loss of Coolant Accident
LWR	Light Water Reactor
MBA	Material Balance Area
MDEP	Multinational Design Evaluation Programme
MPMO	Major Projects Management Office
MUF	Material Unaccounted For
NDPB	Non Departmental Public Body (UK)
NISA	Nuclear and Industrial Safety Agency (Japan)
NPP	Nuclear Power Plant
NRA	Nuclear Regulation Authority (Japan)
NRU	National Research Universal (reactor)
NRX	National Research Experimental (reactor)
NPP	Nuclear Power Plant
ONR	Office for Nuclear Regulation (UK)
PHWR	Pressurized Heavy Water Reactor
PWR	Pressurized Water Reactor
PSA	Probabilistic Safety Analysis
PSR	Periodic Safety Review
RCS	Reactor Coolant System
RIDM	Risk-Informed Decision Making
RSAC	Reactor Safety Advisory Committee (Canada, historical)
SAPs	Safety Assessment Principles (UK)
SAM	Severe Accident Management
SER	State Evaluation Report
SFAIRP	So Far As Is Reasonably Practicable (UK)

SIR	Safeguards Implementation Report
SIS	Systems Important to Safety
SRP	Standard Review Plan (US)
SRP	Staff Review Procedure (Canada)
SSC	Systems, Structures and Components
STUK	Säteilyturvakeskus (Radiation and Nuclear Safety Authority, Finland)
Sv	Sievert, a unit of radiation dose
TAG	Technical Assessment Guide (UK)
TOR	Tolerability of Risk (UK)
TSO	Technical Support Organization
TMI	Three Mile Island
USNRC	United States Nuclear Regulatory Commission
WENRA	Western European Nuclear Regulators' Association

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