

IAEA SAFETY STANDARDS
for protecting people and the environment



Step 7

Licensing Process for Nuclear Installations
DS539
(revision of SSG-12)

DRAFT SAFETY GUIDE

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1. INTRODUCTION

BACKGROUND

1.1 Achievement of the highest level of safety that can reasonably be achieved in relation to nuclear installations requires an effective governmental, legal and regulatory framework — including a regulatory body with well defined responsibilities and functions — as well as qualified vendors, manufacturers and operating organizations. The authorization of nuclear installations (and, where appropriate, of activities undertaken at such installations) through a process of licensing is one of the core functions of a regulatory body. This process may result in the granting of one or more licences during the lifetime of a nuclear installation, depending on the regulatory framework.

1.2 This Safety Guide provides recommendations on meeting the requirements relating to authorization¹ by the regulatory body (in particular, Requirements 23 and 24) established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1].

1.3 Figure 1 shows the main stages dealt with in this Safety Guide regarding the licensing process. These stages include the six major stages of the lifetime of a nuclear installation as defined in the IAEA Nuclear Safety and Security Glossary [2]. Past experience has shown that there is some overlapping of these stages; that is, one stage may start before the previous one is fully completed. Moreover, in a given stage, there may be one or more ‘hold points’ or required licensing actions, set by national legislation and/or regulatory requirements, such as first concrete, installation of major safety significant equipment, entering commissioning, etc.

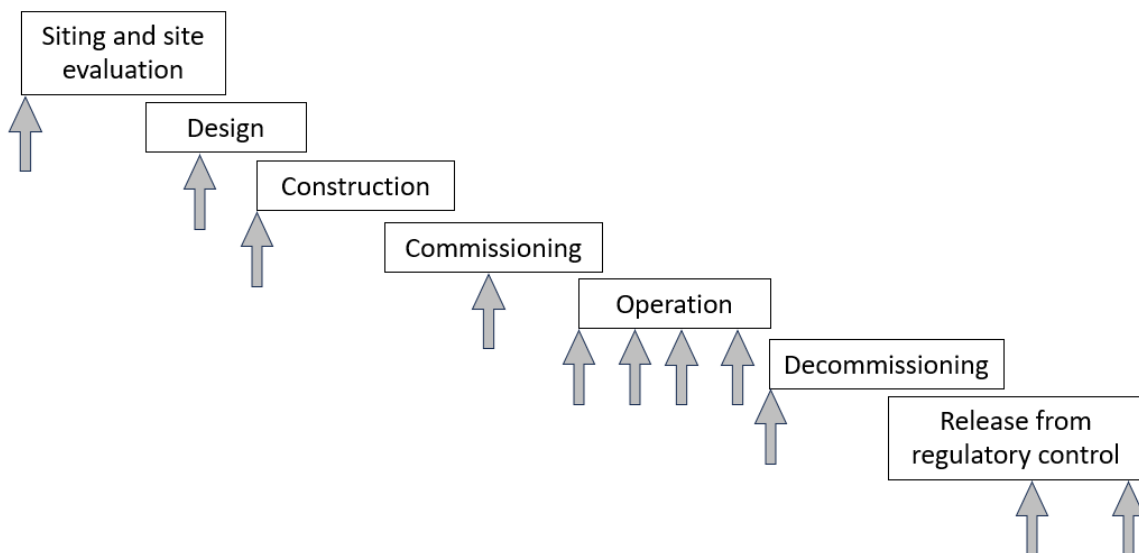


FIG. 1. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.

¹ Authorization to operate a facility or to conduct an activity may be granted by the regulatory body or by another governmental body to an operator (an operating organization or a person). ‘Authorization’ takes the form of a written permission which could include, for example, licensing, certification or registration. See Ref. [2].

26 Licensing activity at these stages and associated hold points or required licensing actions give
27 the regulatory body the power to ensure through safety assessment that risks to people and to
28 the environment from nuclear installations and their activities are properly controlled by the
29 persons or organizations responsible for the nuclear installations and their activities.

30 1.4 This Safety Guide supersedes IAEA Safety Standards Series No. SSG-12, Licensing
31 Process for Nuclear Installations².

32
33 OBJECTIVE

34
35 1.5 The purpose of this Safety Guide is to provide recommendations on developing a
36 licensing process to be applied by regulatory bodies for granting licences for nuclear
37 installations and their activities. This includes the topics and documents that should be
38 considered in the licensing process throughout the lifetime of the nuclear installation,
39 irrespective of the number of licensing steps or hold points imposed on the licensee.

40
41 SCOPE

42
43 1.6 This Safety Guide provides recommendations on how the licensing process should be
44 applied at the various stages of the lifetime of a nuclear installation³ (siting and site evaluation,
45 design, construction, commissioning, operation and decommissioning) until release from
46 regulatory control. Interactions between the regulatory body and the applicant or licensee
47 (including during pre-licensing) are also discussed. Recommendations on the application by a
48 regulatory body of a graded approach to the licensing process are also provided in this Safety
49 Guide.

50 1.7 While this Safety Guide focuses on safety at nuclear installations, security and safeguards
51 are also critical considerations, and interfaces between safety, security and safeguards aspects
52 need also to be considered and evaluated by the regulatory body during the licensing process.
53 The IAEA Nuclear Security Series covers security issues at authorized installations, and
54 aspects of safeguards are covered by further publications, as noted in the IAEA Safeguards
55 Glossary 2022 Edition [3].

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59

² INTERNATIONAL ATOMIC ENERGY AGENCY, Licensing Process for Nuclear Installations, IAEA Safety Standards Series No. SSG-12, IAEA, Vienna (2010).

³ A nuclear installation is defined as “Any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and disposal facilities for radioactive waste.” [2] Similar recommendations on the licensing process for disposal facilities for radioactive waste are provided in other IAEA Safety Standards (SSR-5, Disposal of Radioactive Waste [2011], and SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste [2012])

60 STRUCTURE

61

62 1.8 Recommendations on the licensing process, including basic licensing principles, the
63 content of a licence, public participation, and the roles and responsibilities of the regulatory
64 body, applicant and licensee, are provided in Section 2. Recommendations specific to the
65 various steps of the licensing process are provided in Section 3. Appendix I provides examples
66 of documents to be submitted to the regulatory body. Appendix II provides recommendations
67 on the licensing of small modular reactors and highlights key aspects of deployment models
68 that should be taken into account throughout the licensing process.

2. GENERAL RECOMMENDATIONS ON THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

DEFINITIONS RELEVANT TO THE LICENSING OF NUCLEAR INSTALLATIONS

2.1 A licence is a legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity [2]. The regulatory body, whose status may vary from one State to another, is one or more authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations [2].

2.2 A licence is a product of the authorization process, usually covering a particular stage of the lifetime of a nuclear installation. The term ‘licensing process’ is often used for nuclear installations; it includes all licensing and authorization processes for a nuclear installation and its activities. Licensing may take different forms, such as certification, granting of a permit, agreement, consent, regulatory approval or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State.

2.3 The holder of a current licence is termed a licensee [2]. The licensee is the person or organization having overall responsibility for a facility or activity [2]. Within the context of this Safety Guide, the licensee is the organization possessing the licence(s) for the pertinent stage(s) of the lifetime of a nuclear installation and its activities. The person or organization having overall responsibility for a nuclear installation is required to apply to the regulatory body for permission to begin or continue to perform certain activities, as specified by the regulatory body (see Requirement 23 of GSR Part 1 (Rev. 1) [1]). A licensee might lose its licence for operation, for instance, but should not be released from its prime responsibility for safety, security and safeguards unless so specified by the regulatory body.

2.4 An applicant is a person or organization who applies to a regulatory body for authorization to undertake specified activities [2].

2.5 Licences and other types of authorizations are granted or denied in accordance with the national legal and governmental framework, and are required to cover all stages of the lifetime of the nuclear installation, which usually include, siting and site evaluation, design, construction, commissioning, operation and decommissioning (see para. 4.29 of GSR Part 1 (Rev. 1) [1]), until the installation is released from regulatory control.

BASIC LICENSING PRINCIPLES FOR NUCLEAR INSTALLATIONS

2.6 The licensing process should be understood by all the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the licensing process should follow a logical order.

2.7 In developing a licensing process, consideration should be given to ‘pre-licensing’ processes, for example, steps that provide for early feedback, and potentially approval, on potential sites and feedback on the design features for construction or operation of nuclear

111 installations. Pre-licensing processes can include early engagement between vendors, licence
112 applicants (or potential applicants) and the regulatory body. This approach may be especially
113 applicable for first-of-a-kind designs and designs with innovative technology that are still in
114 various stages of development (see also para. 2.28). A pre-licensing process could be designed
115 to help minimize duplication of effort through the different steps and, where possible, allow
116 for some steps to be conducted in parallel. When used, it should establish a clear division of
117 responsibilities at the various steps, between regulators, vendors and operating organizations
118 and could include options for early public information. Any such processes should ensure that
119 the most important safety issues (including their interactions with security and safeguards) are
120 dealt with properly in the pre-licensing phase. Pre-licensing does not replace the licensing
121 process and does not provide a certification. Further recommendations are provided in para.
122 3.2.

123 2.8 Licences may be granted:

- 124 (a) For a specific time period (e.g. 10 years, 40 years), or for a specific stage in the lifetime
125 of the nuclear installation (e.g. construction, operation). In such a case, a mechanism
126 should be established to ensure that the person or organization responsible for the nuclear
127 installation and its activities remains responsible for safety, security and safeguards at
128 the installation, even if the licence has expired, unless the site has been removed from
129 regulatory control;
- 130 (b) For an indefinite period of time (a permanent licence), under certain conditions and until
131 the licence is officially terminated by the regulatory body;
- 132 (c) For a specific activity or a specific condition of the nuclear installation (e.g. temporary
133 storage of spent fuel).

134
135 2.9 The licensing process involves demonstration of the fulfilment of a set of regulatory
136 requirements applicable to a nuclear installation and formal submissions by an applicant. The
137 licensing process may also include agreements and commitments made between the regulatory
138 body, other authorities, and/or the applicant.

139 2.10 The legal framework of the State is required to set out the responsibilities for issuing a
140 licence or other type of authorization and, in particular, determine who is empowered to issue
141 licences or other authorizations (see Requirements 2 and 3 of GSR Part 1 (Rev. 1) [1]).
142 Depending on the system used in the particular State, different authorizations may be issued
143 by different authorities.

144 2.11 Once an application has been accepted and a licence has been issued, subsequent
145 licensing process activities and arrangements may be undertaken between the licensee and the
146 regulatory body. These may include requests for additional documentation or demonstration or
147 for carrying out further activities, including, in some States, the construction of additional
148 facilities on the site.

149 2.12 Requirement 23 of GSR Part 1 (Rev. 1) [1] states:

150 “Authorization by the regulatory body, including specification of the conditions
151 necessary for safety, shall be a prerequisite for all those facilities and activities that are
152 not either explicitly exempted or approved by means of a notification process.”

- 153
154 2.13 Requirement 24 of GSR Part 1 (Rev. 1) [1] states:
- 155 “The applicant shall be required to submit an adequate demonstration of safety in support
156 of an application for the authorization of a facility or an activity.”
157
- 158 2.14 Requirement 7 of GSR Part 1 (Rev. 1) [1] states:
- 159 “Where several authorities have responsibilities for safety within the regulatory
160 framework for safety, the government shall make provision for the effective coordination
161 of their regulatory functions, to avoid any omissions or undue duplication and to avoid
162 conflicting requirements being placed on authorized parties.”
163
- 164 2.15 Procedures for evaluating, approving, denying, and issuing authorizations for each stage
165 of the lifetime of the nuclear installation and for each type of installation should be prepared
166 by the regulatory body, to ensure that all necessary steps have been taken prior to the granting
167 of a licence.
- 168 2.16 Licence conditions are additional specific obligations with the force of law. Licence
169 conditions should be incorporated into the licence for a nuclear installation, to supplement
170 general requirements or to make them more precise, if necessary. Licences should state
171 explicitly, or should include by reference or attachment, all conditions imposed by the
172 regulatory body.
- 173 2.17 Licence conditions should cover, as appropriate, safety related aspects affecting the siting
174 and site evaluation, design, construction, commissioning, operation and decommissioning of
175 the nuclear installation and its subsequent release from regulatory control, so as to enable
176 effective regulatory control at all stages. These conditions should cover important aspects,
177 including but not limited to, design, radiation protection, maintenance programmes, emergency
178 planning and procedures, modifications, the management system, operational limits and
179 conditions, operating procedures, radioactive waste management, arrangements for
180 decommissioning, nuclear security, cybersecurity, safeguards provisions, nuclear liability
181 (insurance), safety analysis, periodic safety review, human and financial resources, fuel
182 management, outages, aging management, safety culture, resources, and authorization of
183 personnel. Licence conditions may refer to, but should not duplicate, regulatory requirements,
184 to avoid discrepancies or inconsistencies when the regulations are revised. License conditions
185 could also include exemptions of nuclear regulations or non-nuclear regulations.
- 186 2.18 Licence conditions may vary in format; however, there are certain basic characteristics
187 to ensure that they are understandable and effective. Each licence condition should be
188 consistent with all other licence conditions in that the fulfilment of one should not conflict with
189 the fulfilment of another or with any other legal requirement. The grading of regulations can
190 help in resolving contradictions. In the case that it is necessary to specify several licence
191 conditions addressing various technical and administrative aspects, it may be useful to group
192 the conditions into categories, such as:
- 193 (a) Licence conditions that set technical limits and thresholds;
194 (b) Licence conditions that specify procedures and modes of operation;
195 (c) Licence conditions pertaining to administrative matters;

- 196 (d) Licence conditions relating to inspection and enforcement;
197 (e) Licence conditions pertaining to the response to abnormal circumstances, including
198 emergency situations.

199

200 2.19 On a particular site, there may be different nuclear installations at different stages of their
201 lifetimes with different licensees and with authorizations or licences having different licensing
202 bases, depending on the type of regulatory control established in the State. In cases where
203 several licensees share common safety related features, arrangements should be made to ensure
204 that overall safety is not compromised, the specific responsibilities of all licensees should be
205 identified.

206 2.20 The documents submitted to the regulatory body within the framework of the licensing
207 process should be updated, as appropriate, during the lifetime of the nuclear installation. These
208 documents should be incorporated as part of the licence, as necessary. The content of such
209 submissions to the regulatory body may be divided or combined into different documents, as
210 appropriate, depending on national regulations, regulatory regimes and practices. Examples of
211 such documents are given in Appendix I; the content and names of these documents may vary
212 from one State to another. For nuclear power plants, primarily, the safety analysis report is an
213 important document for the entire licensing process; recommendations on the format and
214 content of safety analysis reports are provided in IAEA Safety Standards Series No. SSG-61,
215 Format and Content of the Safety Analysis Report for Nuclear Power Plants [4].

216 2.21 Licensing principles should be established in the legal and regulatory framework.
217 Examples of licensing principles are:

218 (a) A facility and/or activity should be authorized only when the regulatory body has
219 confirmed that the facility or activity is going to be used or conducted in a manner that
220 does not pose an undue risk to workers, the public or the environment. This should
221 include confirmation that the applicant has the organizational capability, organizational
222 structures, adequacy of resources, competence of managers and staff, and
223 appropriateness of management arrangements to fulfil its safety obligations as the
224 operating organization of the nuclear installation. This applies to a new licence, licence
225 renewal, and the transfer of a licence.

226 (b) The regulatory framework for dealing with authorization requests should be clear,
227 especially the process for applying for a licence or authorization, including the
228 expectations for what constitutes a complete application.

229 (c) The regulations presenting the licensing and approval processes should explicitly
230 describe the regime to be followed by the applicant in its descriptions and justifications
231 of the safety case in each design area of the licensing process.

232 (d) The licensing of a nuclear installation should be based on predefined documents that are
233 to be submitted to the regulatory body by the person or organization responsible for the
234 nuclear installation and its activities. These documents are required to be reviewed by
235 the regulatory body (see Requirement 25 of GSR Part 1 (Rev. 1) [1]) and, where required,
236 should be updated regularly by the licensee, as indicated in licence conditions or
237 regulations.

238 (e) Expenses associated with the licensing process and the person or organization that will
239 be charged these expenses, if they are not the responsibility of the State, should be clearly
240 specified.

- 241 (f) A clear and explicit set of requirements, criteria and standards forming the licensing basis
242 should be defined by regulation and by the regulatory body.
- 243 (g) Nuclear security and emergency preparedness requirements should be predefined and
244 should be considered in the licensing process.
- 245 (h) A graded approach is required to be taken by the regulatory body when performing
246 reviews, assessments or inspections throughout the authorization or licensing process
247 (see Requirements 26 and 29 of GSR Part 1 (Rev. 1) [1]). Such an approach should be
248 reflected in regulations and/or guides.
- 249 (i) The licensing process should be transparent to the public, and any licence or authorization
250 should be published or made available to the public, except for security sensitive and/or
251 commercial proprietary information.
- 252 (j) The scope of the licence (the site, a nuclear installation, maximum number of modules
253 on the site at one time, parts of a nuclear installation and activities, or a series of
254 authorizations), its validity period and any incorporated conditions should be clearly
255 defined by the regulatory body.
- 256 (k) The regulatory body should include conditions in the licence, as appropriate.
- 257 (l) A licence may be transferred, depending on national regulations; however, this should be
258 done only with the authorization of the regulatory body, which may attach provisions and
259 conditions to the transfer.
- 260 (m) The applicant and the regulatory body should take into account international and industry
261 good practices, as appropriate, throughout the licensing process.
- 262 (n) The analysis approach to safety should be clearly defined, including the use of analytical
263 tools and deterministic and probabilistic methodologies ~~and analytical tools, for which~~
264 clear acceptance criteria should be set by the regulatory body.
- 265 (o) Safety reviews are required to be performed by the licensee either on a periodic basis or
266 as required by the regulatory body (see para. 4.39A of GSR Part 1 (Rev. 1) [1]), and the
267 results should be submitted to the regulatory body for review and assessment.
268 Appropriate regulatory decisions may then follow, including a decision to suspend the
269 licence, if deemed necessary.
- 270 (p) The prime responsibility for safety is assigned to and assumed by the person or
271 organization responsible for any facilities and activities that give rise to radiation risks
272 (see Requirement 5 of GSR Part 1 (Rev. 1) [1]). Compliance with regulations and
273 requirements imposed by the regulatory body does not relieve the person or organization
274 responsible for any nuclear installations and their activities of the prime responsibility
275 for safety. The person or organization responsible for any nuclear installations and their
276 activities should demonstrate to the satisfaction of the regulatory body that this prime
277 responsibility has been and is likely to continue to be fulfilled.
- 278 (q) Clear conditions should be established for public participation in the licensing process
279 (see paras 2.46–2.49).
- 280 (r) Interfaces between safety, security and safeguards should be addressed to ensure the
281 accomplishment of the objectives and requirements for all three areas, including the
282 integration of emergency management plans with safety and security considerations, and
283 the licensee’s proposed means of addressing these interfaces should be evaluated by the
284 regulatory body in the licensing process. Special attention should be paid to cases where
285 different regulatory bodies are involved in these aspects, to ensure there is no gap in
286 responsibilities.
- 287 (s) The means of challenging or appealing against a licence or part of a licence should be
288 made clear by the regulatory body or within the regulatory framework.
- 289 (t) The site boundaries should be clearly defined and justified based on safety (and security)

290 considerations.

291

292 2.22 The legislative and regulatory framework is required to enable unfettered access for
293 regulatory staff to any facility, any activity and any documents related to safety and considered
294 necessary for granting licences and authorizations (see para. 2.13 of GSR Part 1 (Rev. 1) [1]).

295 2.23 The regulatory framework should establish requirements or conditions (depending on
296 factors such as the nature of the changes, the safety significance and the magnitude of the risks
297 involved) that may require prior review, assessment and approval by the regulatory body of
298 changes or modifications to the site (including a transfer of a licence to another organization),
299 the nuclear installation, the organizational structure of the licensee, procedures, processes or
300 plans for future activities (e.g. decommissioning), at any stage of the life of the nuclear
301 installation. At any stage of the nuclear installation's lifetime, changes or modifications to the
302 site (including a licence transfer to another organization), the nuclear installation, the
303 organizational structure of the licensee, procedures, processes or plans for future activities (e.g.
304 decommissioning) may require (depending on factors such as the nature of the changes and the
305 magnitude of the risks involved) prior review, assessment and approval by the regulatory body
306 and revision of the licence or certain licence conditions. Changes or modifications to a nuclear
307 installation may include the replacement of major components or subsystems and, in some
308 cases, wholesale replacement of the facility with a new or refurbished one.

309 2.24 Arrangements to address the interfaces between safety, security and safeguards are
310 required (see Requirement 12 of GSR Part 1 (Rev. 1) [1]). Synergies that exist between the
311 processes for safety, security and safeguards should be fully exploited. Safety, security and
312 safeguards measures should be designed and implemented in an integrated manner so that they
313 do not compromise each other. Potentially conflicting needs resulting from safety, security and
314 safeguards considerations should be identified as early as possible in the licensing process and
315 should be carefully analysed to provide a mutually acceptable solution with respect to all three
316 areas. Additional information on addressing the safety–security interface is provided in Refs
317 [5], [6] and [7].

318

319 OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE REGULATORY BODY FOR 320 LICENSING OF NUCLEAR INSTALLATIONS

321

322 2.25 The regulatory framework should empower the regulatory body to make regulatory
323 decisions and to grant, amend, suspend, transfer, or revoke licences, conditions or
324 authorizations, as appropriate.

325 2.26 Paragraphs 2.27–2.41 provide recommendations on the general obligations, roles and
326 responsibilities of the regulatory body throughout the licensing process; stage-specific
327 responsibilities are covered in Section 3. Recommendations on the organization and functions
328 of the regulatory body are provided in IAEA Safety Standards Series Nos GSG-12,
329 Organization, Management and Staffing of the Regulatory Body for Safety [8], and GSG-13
330 Functions and Processes of the Regulatory Body for Safety [9].

331 2.27 The procedures or guidelines for applying for a new licence should be published by the

332 regulatory body, together with the address to which the application should be sent. It should be
333 made clear what the application should include, for example:

- 334 (a) The name, address and any additional contact information of the applicant;
- 335 (b) The site for which the application is being made;
- 336 (c) The nature of the activity that the applicant wishes to undertake, the main risks associated
337 with the activity and the time duration for the required license;
- 338 (d) Details of any relevant existing licence;
- 339 (e) An environmental assessment report, if required by national legislation;
- 340 (f) Information on the ownership structure. This would include whether the installation or
341 activity is fully or primarily owned or controlled by a person from another State or
342 organization;
- 343 (g) A preliminary safety analysis report.

344
345 2.28 Before an applicant submits an application, the regulatory body should implement a
346 preparatory phase, during which basic licensing requirements are set out and the process to be
347 followed is made clear to the applicant. This may include specification of, for example, the
348 language, units and format of the proposed application. During this phase, the staff of the
349 regulatory body should be trained so they have sufficient knowledge of the design of nuclear
350 installations that may be proposed. The basic requirements set out in the preparatory phase
351 should be design-neutral so that several designs may be considered at the beginning of a project
352 to build a nuclear installation. In addition, possible exemptions on local non-nuclear specific
353 rules (e.g. rules for civil works, fire regulations, requirements from environmental permitting)
354 may be managed with regulators in the preparatory stage. Nevertheless, detailed and explicit
355 design requirements should be developed during the early phases of the project.

356 2.29 Pre-licensing interactions (see para. 2.7) of the regulatory body with the vendor and the
357 potential licensee are encouraged. These pre-licensing interactions not only benefit the
358 regulatory body, but they also benefit vendors and potential licensees because they allow for
359 early identification and understanding of technical and policy issues that could affect licensing.
360 This is particularly important for first-of-a-kind installations, and for matters relating to
361 radioactive waste management and decommissioning, as these are aspects that are particularly
362 important to be considered at the earliest stages of the development of the design. Design
363 features and an assessment of safety, security, and safeguards needs, may be addressed in pre-
364 licensing interactions, including the interfaces between each of these areas. At an early pre-
365 licensing stage, the vendor and the potential licensee may not have yet developed the
366 arrangements and requirements that would be needed to be demonstrated during the licensing
367 processes.

368 2.30 The regulatory body should develop regulations for the licensing process of nuclear
369 installations and should provide guidelines for applicants in order to provide clarity and
370 transparency in the licensing process.

371 2.31 The regulatory framework should empower the regulatory body to conduct reviews,
372 assessments and inspections of:

- 373 (a) The applicant's evidence of and plans to meet regulatory requirements regarding its
374 organizational capability (including the competence of contractors) and the safety case
375 for the nuclear installation and related activities;

- 376 (b) The descriptions and claims in the documentation of the applicant or licensee;
377 (c) The licensee's compliance with regulations, safety objectives, principles, requirements
378 and criteria, the safety cases and safety analyses, and the conditions of the licence;
379 (d) The continued organizational capability of the licensee (and of its contractors and
380 subcontractors) to meet the actual authorization, licence or regulatory requirements.

381
382 2.32 Early assessment of the competence and capability of the applicant should be conducted
383 to ensure that the applicant will be able to manage the later phases of the project for the nuclear
384 installation. The applicant should be encouraged to conduct a resourcing strategy at the very
385 beginning of the project to evaluate the staff and competencies it will need during the different
386 project phases. The applicant should give consideration to how and from where it will recruit
387 such staff and how it will find additional external technical support and advice when needed.
388 This is particularly relevant for applicants that have not previously applied for or held a licence
389 for a nuclear installation.

390 2.33 The regulatory body is required to establish a management system (see para. 1.7 of IAEA
391 Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [10]), and this
392 should include dealing with licence applications, both initial applications and subsequent
393 applications. The system should set out arrangements for requesting further information from
394 the licensee, for carrying out review and assessment of the licensee's application and for
395 carrying out inspections, as appropriate and necessary. The system should define
396 responsibilities within the regulatory body for making the decision on whether to accept the
397 application. The applicant or licensee should be informed of the decision in an appropriate
398 manner, in accordance with the legal framework. All documentation relevant to the issuing of
399 a licence or authorization should be recorded and kept for the lifetime of the installation or
400 activity, and for a specified period beyond such lifetime, in accordance with legal requirements.

401 2.34 The nature of the review, assessment and inspection by the regulatory body will depend
402 on the type of nuclear installation, its activities and the stage in the lifetime of the nuclear
403 installation, and will follow a graded approach commensurate with the radiation risks of the
404 installation, as outlined in GSR Part 1 (Rev.1) [1].

405 2.35 The regulatory body may request a reassessment of safety at the nuclear installation and
406 of the safety of its activities in the light of the following:

- 407 (a) Experience relevant to safety that has been gained at the nuclear installation, at similar
408 nuclear installations and at other relevant nuclear and non-nuclear installations;
409 (b) Information from relevant tests and from research and development programmes, and
410 new knowledge of technical matters;
411 (c) Changes in or modifications to the licensed activities important to the safety of a nuclear
412 installation
413 (d) Changes in the regulatory framework, regulations and guides;
414 (e) Changes in the licensee;
415 (f) Changes in the site conditions;
416 (g) Changes in the facility's preparedness to handle emergency situations;
417 (h) After a safety-significant event or accident.

418
419 2.36 Following such a reassessment, the stage in the lifetime of the nuclear installation may

420 be halted or made subject to specific conditions, depending on the safety issue involved; the
421 stage should be authorized to continue only once the regulatory body is satisfied with the
422 licensee's demonstration of safety. Specific conditions set by the regulatory body may include
423 measures to be taken within a specified time frame.

424 2.37 As part of the licensing process and Bbefore a licence is granted, the regulatory body
425 should monitor ~~verify that~~ the applicant or licensee to verify that it has, as appropriate:

- 426 (a) A suitable management system (see GSR Part 2 [10]);
427 (b) Clear procedures for analysing and endorsing any modifications (including temporary
428 modifications) having an impact on safety (see also para. 2.38);
429 (c) Certificates of sufficient liability insurance or other financial security;
430 (d) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive
431 positions (further information is available in IAEA Nuclear Security Series No. NST065,
432 Establishment and Implementation of a Trustworthiness Programme in Nuclear Security
433 [11]).

434
435 2.38 After granting of the first license (e.g., the construction license), the regulatory body
436 should ensure that proposed modifications are categorized by the licensee in accordance with
437 their safety significance. This categorization should follow an established procedure, which
438 may be subject to agreement or approval by the regulatory body. Modifications that are
439 categorized as significant to safety should be submitted to the regulatory body for review and
440 approval or agreement. The regulatory body should inspect compliance with categorization
441 procedures on a regular basis. Further recommendations related to nuclear power plant
442 operation are provided in IAEA Safety Standards Series No. SSG-71, Modifications to Nuclear
443 Power Plants [12].

444 2.39 Throughout the licensing process, the regulatory body should ensure that the licensee has
445 an established feedback system for learning from experience (regarding engineering, human
446 and organizational aspects). Review, assessment and inspections performed by the regulatory
447 body to confirm the existence and the application of such experience feedback should also be
448 considered (further information is available in SSG-50, Operating Experience Feedback for
449 Nuclear Installations [13]).

450 2.40 For each stage of the installation's lifetime, the regulatory body should impose
451 requirements or conditions on what kind of information and reports should be sent to the
452 regulator body and their periodicity.

453 2.41 Regulatory provisions should be established to ensure that, if licence expiry dates are
454 established, they are such that the person or organization in charge of the nuclear installation
455 is not relieved of the prime responsibility for safety until the regulatory body so decides.

456

457 OBLIGATIONS, ROLES AND RESPONSIBILITIES OF THE APPLICANT OR LICENSEE

458

459 2.42 The applicant or licensee for a nuclear installation has the following obligations, roles
460 and responsibilities:

- 461 (a) The applicant or licensee should prepare, independently review, and submit a
462 comprehensive application to the regulatory body that demonstrates that priority is given
463 to safety, security and safeguards; that is, that the level of safety, security and safeguards
464 meets regulatory requirements and that safety, security and safeguards will be maintained
465 at the site for the entire lifetime of the nuclear installation.
- 466 (b) The applicant or licensee should carry out an independent verification of the safety
467 assessment before it is submitted to the regulatory body for review.
- 468 (c) The applicant or licensee should have the capability within its own organization (either
469 on-site or within the organization as a whole), even when outsourcing licensed activities,
470 to understand the design basis and safety analyses for the nuclear installation, and the
471 limits and conditions under which it is to be operated.
- 472 (d) The applicant or licensee should exercise control over all of the work of contractors,
473 especially when outsourcing licensed activities, understand the safety significance of this
474 work ('informed customer' capability) and take responsibility for its implementation.
- 475 (e) The applicant or licensee should submit a procedure or description to the regulatory body
476 of the process for configuration management, including managing modifications, which
477 may be subject to approval by the regulatory body. Alternatively, requirements for
478 dealing with modifications may be established directly in the regulations, and the
479 regulatory body may then perform inspections to verify that the licensee meets such
480 requirements.
- 481 (f) The applicant or licensee should have capability of an informed customer and a formal
482 and effective external relationship with the original design organization or an acceptable
483 alternative.
- 484 (g) The applicant or licensee should assess safety in a systematic manner and on a regular
485 basis and perform necessary improvements, as required to maintain the level of safety.
- 486 (h) The applicant or licensee should implement nuclear security and emergency
487 preparedness measures at the nuclear installation.
- 488 (i) The applicant or licensee should understand the obligations at a nuclear installation for
489 accounting for, and control of, nuclear material and radioactive material.
- 490 (j) The applicant or licensee should demonstrate in its application for a licence that it has,
491 or will have when necessary, and will continue to maintain:
- 492 (k) Adequate financial resources (e.g. depending on national legislation and regulation, for
493 regulatory fees and liability insurance, and for funding of the construction, operation and
494 decommissioning stages and of maintenance).
- 495 (l) Adequate human resources to safely construct, maintain, operate and decommission the
496 nuclear installation, and to ensure that regulatory requirements and safety standards are
497 met and will continue to be met.
- 498 (m) The applicant or licensee should be able to demonstrate that contractual arrangements do
499 not compromise the independence or safety of its decision making process.

500

501 2.43 The licensee should put into place procedures within its management system for each
502 stage of the lifetime of the nuclear installation, including, where appropriate, procedures for
503 the provision of independent advice. Throughout the licensing process, the regulatory body
504 should ensure that the licensee properly carries out this task. Procedures should be put into
505 place:

- 506 (a) For controlling the nuclear installation within the limits specified in regulations and/ or
507 licence conditions;

- 508 (b) For managing anticipated operational occurrences and accident conditions;
509 (c) For responding to a nuclear or radiological emergency.

510

511 These procedures should be periodically reviewed and revised, as appropriate, to take into
512 account operating experience, modifications, and national and international good practices.

513

514 MAIN CONTENTS OF A LICENCE FOR A NUCLEAR INSTALLATION

515

516 2.44 The licence for a nuclear installation should include the following elements (unless
517 specified elsewhere in the legal and regulatory framework):

- 518 (a) A unique licence identification.
519 (b) The issuing authority: the laws and regulations under which the licence is issued; the
520 official designations of those who are empowered by those laws or regulations to issue
521 the licence and whose signature and stamp should appear on the licence; and the authority
522 to which the licensee will be accountable under the terms of the licence.
523 (c) Identification of the individual or organization legally responsible for the licensed
524 installation or activity.
525 (d) A sufficiently detailed description of the nuclear installation, its location and its activities,
526 including a clear depiction and description of the site boundaries, and other drawings, as
527 appropriate.
528 (e) The maximum allowable inventories of radioactive sources, including the identification
529 of future expansion of the installation if relevant.
530 (f) The procedure for notifying the regulatory body of any modifications that are significant
531 to safety.
532 (g) The obligations of the licensee with respect to both safety at the installation and the safety
533 of its equipment, radiation source(s), personnel, the public and the environment.
534 (h) Any limits on operation and use (e.g. dose limits, discharge limits, emergency action
535 levels, limits on the duration of the licence).
536 (i) Any separate additional authorizations that the licensee is required to obtain from the
537 regulatory body.
538 (j) The procedure for reporting events and incidents at the installation.
539 (k) The procedure for providing routine reports to the regulatory body.
540 (l) The requirements for retention of records by the person or organization responsible for
541 the nuclear installation and its activities, including the time periods for which records
542 should be retained.
543 (m) The requirements for nuclear security at the installation.
544 (n) The requirements for arrangements for emergency preparedness.
545 (o) The procedures for changing any information stated in the licence.
546 (o) The documentary basis: the documents in support of the application and those prepared
547 and used by the regulatory body in the review and assessment process, which together
548 form the basis for issuing the licence.
549 (p) The relationship to other licences; that is, whether the licence is contingent upon a prior
550 authorization or is a prerequisite for a future authorization. Mechanisms should be
551 established so that expiry of an authorization is avoided (if an expiry date is established
552 by the regulatory regime).
553 (q) Procedures for, information about and identification of the legal framework for
554 challenging the licence or part of the licence.

555 (r) Licence conditions dealing with safety aspects of the installation and its activities.

556 (s) The length of the license.

557

558 2.45 The licence conditions (see paras 2.16–2.18) may include or refer to: technical limits and
559 conditions; a system for reporting events, modifications and incidents to the regulatory body;
560 and other requirements, depending on the magnitude of the risk, the nature of the nuclear
561 installation, the activities performed and the stage in the nuclear installation’s lifetime. More
562 recommendations are provided in Section 3.

563 PUBLIC PARTICIPATION IN THE LICENSING OF NUCLEAR INSTALLATIONS

564

565 2.46 The public should be given an opportunity to present their views during certain steps of
566 the licensing process for a nuclear installation, as appropriate. If a site is near a State’s national
567 border, there should be appropriate cooperation, including public participation, with
568 neighbouring State(s) in the vicinity of the nuclear installation.

569 2.47 Transparency, along with public participation and involvement in the regulatory process,
570 reinforces the credibility of the regulatory body and enhances local public confidence in the
571 nuclear regulatory regime. The process for public participation should allow individuals or
572 societal groups to challenge the issuing of a licence or authorization if it appears to jeopardize
573 health or safety.

574 2.48 Throughout the lifetime of the nuclear installation, the public participation process,
575 including participation of local, national and international interested parties, should be open,
576 transparent, well described and balanced, and should ensure that security sensitivities and
577 commercial proprietary information are respected. For example:

578 (a) The regulatory body and licensee should provide easy access to relevant and
579 comprehensive information relating to safety and to the licensing process and licensed
580 activities. Such information should be published where it can be easily accessed, such as
581 on the internet and in the mass media.

582 (b) Formal meetings, formal hearings or other appropriate means of communication should
583 be:

584 (i) Open to the public, the media and other interested parties;

585 (ii) Announced a reasonable period of time before the meeting or hearing takes place.

586 (c) The public should be given the opportunity to present their opinions at meetings and
587 formal hearings and via other appropriate means of communication.

588 (d) Comments from the public should be addressed at all steps of the licensing process.

589 2.49 A process for consideration and resolution of concerns should be established in national
590 regulations and guides.

591 GRADED APPROACH TO THE LICENSING OF NUCLEAR INSTALLATIONS

592

593 2.50 Paragraph 3.24 of IAEA Safety Standards Series No. SF-1, Fundamental Safety
594 Principles [14] states that “The resources devoted to safety by the licensee, and the scope and
595 stringency of regulations and their application, have to be commensurate with the magnitude

596 of the radiation risks and their amenability to control.” To apply this principle, a graded
597 approach is required to be used in the licensing process for different types of nuclear installation
598 and the different levels of risks that they pose (see para. 4.33 of GSR Part 1 (Rev. 1) [1]).
599 Application of a graded approach by the regulatory body focuses the way that an installation
600 and its activities are assessed, inspected and authorized on the basis of risks, without unduly
601 limiting the operation of the nuclear installation or the conduct of its activities.

602 2.51 A graded approach is required to be used by the regulatory body in determining the scope,
603 extent and level of detail of, and the effort to be devoted to, review, assessment and inspection,
604 and the number of authorizations for any particular nuclear installation and its activities (see
605 Requirement 26 of GSR Part 1 (Rev. 1) [1]).

606 2.52 The main factor taken into consideration in the application of a graded approach to
607 determining the level of regulatory control should be the magnitude of the risks associated with
608 the activities performed at the nuclear installation. Account should be taken of occupational
609 doses, radioactive discharges and the generation of radioactive waste during operation, as well
610 as the potential consequences of anticipated operational occurrences and accidents, including
611 their probability of occurrence and the possibility of occurrence of very low probability events
612 with potentially high consequences.

613 2.53 A graded approach to safety assessment should also take account of other relevant factors
614 such as the maturity of the licensee, the maturity of the technology (see Safety Demonstration
615 of Innovative Technology in Reactor Designs [15]) and complexity and ageing related issues
616 relating to the nuclear installation and its activities. Maturity relates to: the use of proven
617 practices and procedures, proven designs and operating experience at similar nuclear
618 installations and for similar activities; uncertainties in the performance of such a nuclear
619 installation or activities; and the availability of competent staff and experienced managers,
620 contractors and suppliers. Complexity relates to: the extent and difficulty of the effort needed
621 to construct, maintain, operate and decommission a nuclear installation or to conduct an
622 activity; the number of the related processes for which control is necessary; the physical and
623 chemical forms of the radioactive material and the extent to which the radioactive material has
624 to be handled; the ~~half-lives~~estimated activity of the radionuclides concerned; the risk and
625 uncertainty associated with activities and the reliability and complexity of structures, systems
626 and components (SSCs) and their accessibility for maintenance, inspection, testing and repair.
627 Similarly, a graded approach should be applied as the nuclear installation progresses through
628 the stages of its lifetime.

629 2.54 The application of a graded approach should be reassessed as the safety assessment
630 progresses. Adjustments to the safety assessment may be made as a better understanding is
631 obtained of the risks associated with the nuclear installation and its activities. The scope, extent
632 and level of detail of, and the effort devoted to, the review, assessment and inspection and the
633 related licensing process should be revised accordingly.

634 2.55 A graded approach should be applied to emergency preparedness and response
635 requirements (see para. 4.19 of GSR Part 7 [16]). If a nuclear installation is sited near industrial
636 sites or population centres, the impact of an emergency could have a significant impact on the
637 nearby industrial site or population. Additionally, the impact of size, technology and possible
638 underground siting of the nuclear installation should be assessed.

3. STEPS OF THE LICENSING PROCESS FOR NUCLEAR INSTALLATIONS

3.1 The licensing process for a nuclear installation will normally include the following steps, depending on national legislation:

- (a) Siting and site evaluation (which may include the environmental impact assessment);
- (b) Design;
- (c) Construction (which may include procurement, manufacturing, and construction stages on the site or off the site);
- (d) Commissioning;
- (e) Operation (which may include maintenance, refuelling, in-service inspection, extended shutdowns and other associated activities);
- (f) Decommissioning (or closure for certain installations);
- (g) Release from regulatory control.

Each step of the licensing process may be divided into several sub-steps or may be merged or combined as appropriate to facilitate the regulatory process. Combining authorizations or licences (e.g. for construction and operation) may also give more predictability to the process for the licensee. At each hold point set down by the regulatory body or in the licensing process, an authorization or a licence from the regulatory body may be required. Conditions may be attached to licences granted at each step and may require that the licensee obtain further, more specific, authorizations or approvals before carrying out particular activities.

ALTERNATIVE REGULATORY PROCESSES FOR COMBINED LICENCES FOR NUCLEAR INSTALLATIONS

3.2 The licensing of nuclear installations typically involves discrete steps, as described in this Safety Guide, especially for States that are planning a first nuclear installation. However, alternative approaches do exist, especially for countries with experience in nuclear power where several similar nuclear installations have already been built and are proven. The licensing process of another country may be adopted or adapted in the regulatory framework to take advantage of similar designs, with the requirement that the standardized (i.e. not site specific) safety cases of the vendors and of an experienced operating organization be later supplemented by site specific and installation specific safety assessments (e.g. environmental impact assessment, confirmation that the site characteristics are compatible with the standardized design). In such contexts, the regulatory body may consider, in advance, early approval of sites and certification of standardized plant designs. International cooperation on design certification may also help to facilitate the licensing process. The regulatory body may also consider using information from another regulatory body to make a regulatory decision, on the basis that the regulatory body receiving the information understands the regulatory basis and considers the local specificities and arrangements. The applicant may then apply in due course for a specific combined licence that authorizes, for example, construction, commissioning and operation. In this approach, the applicant may reference the early site permit and the certified standard design in its application. Depending on the national legal and regulatory framework, safety and environmental issues may have to be resolved before the site

683 or design licence is granted, and the resolution of such issues should be considered final. Pre-
684 licensing interactions between the applicant and the regulatory body may be beneficial for such
685 combined licences. The elements of such an alternative licensing process might include the
686 following steps:

- 687 (a) Early site permits. In such a licensing process, a prospective applicant for a licence for
688 construction, commissioning and operation can apply for approval for use of a specific
689 site or sites, notwithstanding the fact that the application for a licence to construct,
690 commission and operate a nuclear installation has not been filed. Regulatory body
691 approval of the site or sites may be done without the applicant having identified a specific
692 design for the nuclear installation.
- 693 (b) Certified standard designs. In such a licensing process, any company may obtain
694 certification of a standardized design for a nuclear installation, notwithstanding the fact
695 that the application for a licence for construction and operation with the certified design
696 has not been filed. The application should typically include bounding site conditions. The
697 regulations should allow for approval to be granted for an essentially complete standard
698 design for an entire nuclear installation. The regulations should require that the
699 application for certification of a standardized design contain sufficient information to
700 enable a final conclusion to be reached on all safety questions associated with the design.
701 Such a certification of a standardized design could help to ensure that two nuclear
702 installations of the same design would not vary significantly from each other, except for
703 variations necessary due to site specific characteristics.
- 704 (c) Manufacturing licence. In such a licensing process, an applicant may apply for a
705 manufacturing licence, to manufacture a nuclear power reactor, notwithstanding that the
706 application for a licence to construct, commission and operate a nuclear installation may
707 not be yet filed. An applicant could be allowed to refer to a certified standard design as
708 part of its application for a manufacturing licence.
- 709 (d) Combined licence. In such a licensing process, an applicant can apply for a single licence
710 to construct, commission and/or operate a nuclear installation. If the licence is issued,
711 and if the installation is constructed in accordance with the requirements set forth in the
712 licence, the regulatory body should then allow the plant to begin operation. In such a
713 regulatory regime, considerable pressure is put on the regulatory body to maintain control
714 over all the licensee's activities. If the licensing process is to be simplified in this manner,
715 the inspection process should be made sufficiently rigorous to ensure that all safety
716 requirements are fulfilled. The regulatory body will then need to have adequate
717 capabilities and resources to manage its own inspection process and to monitor all safety
718 related activities during the construction, commissioning and operation stages. Key hold
719 points — such as fuel loading, power increase, addition of another type of installation or
720 modules, or other technical points, as appropriate — may be imposed on the licensee. In
721 such a simplified licensing process, an applicant could be allowed to refer to an early site
722 permit and a standard design certification as part of its application for a combined licence
723 for construction, commissioning and operation of a nuclear installation. The regulatory
724 body would then consider as resolved all matters that were resolved in connection with
725 the granting of the early site permit and the standard design certification. The applicant,
726 however, could be allowed to request an exemption from one or more elements of the
727 certified design; such exemptions should be granted if regulatory requirements are
728 fulfilled and safety is considered adequate after review and assessment by the regulatory
729 body.

730

731 APPROVAL OF SITING AND SITE EVALUATION FOR A NUCLEAR INSTALLATION

732

733 3.3 Requirements for site evaluation are established in IAEA Safety Standards Series No.
734 SSR-1, Site Evaluation for Nuclear Installations [17].

735 3.4 The siting process for a nuclear installation generally consists of investigation of a large
736 region to select one or more preferred candidate sites, followed by a detailed evaluation of
737 those candidate sites. After site selection, the regulatory body should be involved in the
738 decision as to the acceptability of the selected site and should have the authority to establish
739 conditions for the site or to reject a proposed site on the basis of safety concerns or
740 environmental impacts, if applicable. For a site close to a State's national border, consultations
741 with neighbouring countries should be performed.

742 3.5 Site evaluation is analysis of those factors at a site that could affect the safety of a
743 facility or activity on that site [2]. This includes site characterization, including identification
744 of external hazards (natural and human induced), and consideration of factors that could affect
745 the safety features of the nuclear installation or its activities and result in a release of radioactive
746 material and could affect the dispersion of such material in the environment. The site evaluation
747 should also consider the potential impact of the nuclear installation and its activities on the
748 environment and the neighbouring population, and a preliminary assessment should be
749 performed to verify that no incompatibilities are foreseen. The feasibility of planning effective
750 emergency response actions on the site and off the site, given the site's geographical and
751 logistical factors (e.g., accessibility for emergency services, population evacuation routes),
752 should be evaluated (see Requirement 13 of SSR-1 [17]).

753 3.6 For a nuclear installation, following site selection, site evaluation typically involves the
754 following stages [2]:

- 755 (a) Site selection stage. One or more preferred candidate sites are selected after the
756 investigation of a large region, the rejection of unsuitable sites, and screening and
757 comparison of the remaining sites.
- 758 (b) Site characterization stage. This stage is further subdivided into:
- 759 — Site verification, in which the suitability of the site to host a nuclear installation is
760 verified, mainly in accordance with predefined site exclusion criteria;
 - 761 — Site confirmation, in which the characteristics of the site necessary for the purposes
762 of analysis and detailed design are determined.
- 763 (c) Pre-operational stage. Studies and investigations begun in the previous stages are
764 continued after the start of site preparation and construction and before the start of
765 operation. The site data obtained allow a final assessment of the simulation models used
766 in the final design.
- 767 (d) Operational stage. Appropriate safety related site evaluation review activities are
768 performed throughout the operating lifetime of the facility, mainly by means of
769 monitoring, periodic safety review.

770

771 3.7 Before on-site construction begins, the regulatory body should issue a formal regulatory
772 decision on the acceptability of the site, which should address how appropriate participation of
773 all interested parties and authorities is to be ensured.

774 **Safety assessment and environmental impact assessment**

775

776 3.8 A radiological study of the region, including an appropriate baseline survey, is required
777 to be performed before commissioning of the nuclear installation (see para.7.3 of SSR-1 [17]).
778 This study and survey should be provided to the regulatory body as the baseline for future
779 analyses following operation of the nuclear installation.

780 3.9 There are a number of factors that are required to be adequately considered in
781 determining the suitability of the site (see Requirement 4 of SSR-1 [17]). Many of these factors
782 may be covered by a specific environmental impact assessment (see IAEA Safety Standards
783 Series No. GSG-10, Prospective Radiological Environmental Impact Assessment for Facilities
784 and Activities [18]). In such cases, the legal relationship between this environmental impact
785 assessment and the licensing process should be established. To meet the requirements
786 established in SSR-1 [17], the following important factors for the licensing process for nuclear
787 installations are required to be reviewed, assessed and inspected by the regulatory body,
788 applying a graded approach, as appropriate:

789 (a) Factors dealing with the risks for the nuclear installation:

790 (i) The range of natural conditions,— (e.g. hydrology, meteorology, geography,
791 topology, vulcanism) and risks and hazards for the site (e.g. ~~seismic hazards,~~
792 ~~geological hazards,~~ hydrological hazards, ~~meteorological hazards,~~ geography,
793 topology, flood hazards, extreme weather hazards, flood and landslide hazards,
794 seismic and other geological hazards, tsunami hazards, external fire hazards),
795 including the effects of climate change in the future.

796 (ii) The range of human induced risks and hazards for the site (e.g. adjacent hazardous
797 industrial facilities, gas pipelines, mining, transport of dangerous goods in the
798 vicinity of the site, air traffic and the potential for aircraft crashes and security
799 risks).

800 (iii) Where multiple nuclear installations are considered for a single site, the site as a
801 whole should be evaluated for interactions between the installations, for example,
802 the potential for an accident at one nuclear installation affecting other nuclear
803 installations on the site, shared services, cumulative effects of discharges and
804 common cause failures. Such interactions should also be considered at the design
805 stage.

806 (iv) The use of the land around the site boundary (including industrial activities)
807 regarding activities or changes that might significantly affect safety and security at
808 the nuclear installation. Such a use should be controlled for the entire lifetime of
809 the nuclear installation.

810 (v) Where a nuclear installation would provide end-products (e.g. power, heat,
811 electricity, hydrogen) to a nearby industrial or municipal user, the interactions and
812 external hazards between the nuclear installation and end-product users should be
813 evaluated for their safety implications. For example, the arrangement should be
814 implemented such that economic considerations of the end-product user should not
815 affect safety of the nuclear installation.

816 (b) Factors dealing with risks for people and the environment, including transboundary
817 aspects (see Ref. [19]), as appropriate:

818 (i) The location of the local population and population density, monitoring of
819 population distribution and human activities in the site vicinity, as well as health

- 820 and socioeconomic aspects;
- 821 (ii) The impact of the location on arrangements for emergency preparedness and
822 response (e.g. the location of adjacent activities, homes, schools, hospitals, prisons
823 and businesses, as well as roads and transport routes, and other types of traffic);
- 824 (iii) The licensee's security of tenure and rights of access, and the relationship between
825 the applicant and the owner of the site area;
- 826 (iv) The existing environmental conditions at the site (e.g. pre-existing contamination;
827 the condition of the air, water, earth, flora and fauna; the quality of the air, soil,
828 groundwater, surface water and deep seated waters);
- 829 (v) The land use and the cultivation types, crops and animal breeding and historical
830 heritage;
- 831 (vi) Marine or aquatic ecology (e.g. of seas, lakes, rivers);
- 832 (vii) The effect of gaseous, liquid and solid discharges (e.g. radioactive, toxic);
- 833 (viii) The potential for heat dissipation (including the ultimate heat sink).
- 834

835 APPROVAL OF THE DESIGN OF A NUCLEAR INSTALLATION

836 3.10 Requirements for the design of installations are established in IAEA Safety Standards
837 Series Nos SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [20], SSR-3, Safety of
838 Research Reactors [21] and SSR-4, Safety of Nuclear Fuel Cycle Facilities [22].

839 3.11 The design stage may include other tasks, such as a 'feasibility study', or a 'pre-
840 licensing' step, depending on the national context (e.g. whether or not the State already has
841 nuclear installations of the same type).

842 3.12 If sites and designs are considered separately early in the project to build a nuclear
843 installation, then the regulatory body or the vendor should establish a definition of 'generic
844 site' and a definition of 'generic design'. The 'generic site' may include consideration of
845 aspects of multiple sites. The 'generic design' may include bounding assumptions on regarding
846 the activities at the installation. A process to ensure that both the site and the design are
847 compatible in the licensing process should also be established, including the assessment of site
848 specific conditions. The site evaluation and the environmental impact assessment should be
849 reviewed and, if necessary, enhanced after the process through which the design is selected.

850 3.13 The regulatory body should review and assess the acceptability of the selected design
851 and should have the authority to approve, agree, comment on, question or reject such designs
852 or parts thereof, as necessary, on the basis of safety concerns.

853 3.14 The design of the proposed nuclear installation should be such that safety requirements
854 can be met in accordance with the design basis. The design basis is the range of conditions and
855 events taken explicitly into account in the design of SSCs and equipment of the nuclear
856 installation, in accordance with established criteria, such that the nuclear installation can
857 withstand them without exceeding authorized limits [2]. The applicant for authorization for
858 construction should submit a basic design to the regulatory body before construction begins.
859 This basic design can be approved or, depending on the regulatory framework, frozen (i.e. no
860 change may be made to the basic design without the regulatory body's review and approval)
861 or partly frozen with a regulatory instrument upon the review and assessment of the regulatory
862 body. During the design, the systematic analysis of the interfaces between safety measures,
863 security measures and safeguards arrangements should be implemented in order to support the

864 demonstration of fulfilment of Requirement 8 of SSR-2/1(Rev. 1) [20], Requirement 11 of
865 SSR-3 [21] and Requirement 75 of SSR-4 [22].

866 3.15 During construction and throughout the lifetime of the nuclear installation, parts of the
867 detailed design may be subject to approval or may be frozen. Such approvals or processes for
868 freezing a detailed design should be undertaken by means of regulatory instruments, and
869 conditions should be attached, as appropriate. If the licence applications for construction and
870 operation are made concurrently (i.e. a combined licence), parts of the detailed design should
871 then be reviewed by the regulatory body in the course of application for the construction and
872 operation licence.

873 3.16 At the design stage, it is important to ensure that SSCs comply with approved or
874 accepted standards, codes and regulatory requirements, including quality assurance (QA)
875 requirements. It is also necessary to ensure that construction work at the nuclear installation
876 can be undertaken in accordance with design specifications and that sufficient suitably
877 qualified and experienced staff are available for design work, supply and manufacture, and for
878 the control of these activities. The regulatory body should ensure that clear and explicit quality
879 requirements are specified by the licensee or applicant for safety related activities. The
880 regulatory body should check, either through the licensee, [applicant](#), or directly, depending on
881 national legislation, whether all organizations and contractors involved in design adequately
882 implement these requirements, and should take appropriate actions if necessary.

883 3.17 Defence in depth is required to be considered in the design and subsequently, in
884 operation (see Requirement 7 of SSR-2/1 (Rev. 1) [20]). Requirement 10 of SSR-3 [21] and
885 Requirement 10 of SSR-4 [22]). Paragraph 3.31 of SF-1 [13] states:

886 “The primary means of preventing and mitigating the consequences of accidents is
887 ‘defence in depth’. Defence in depth is implemented primarily through the combination
888 of a number of consecutive and independent levels of protection that would have to fail
889 before harmful effects could be caused to people or to the environment. If one level of
890 protection or barrier were to fail, the subsequent level or barrier would be available.
891 When properly implemented, defence in depth ensures that no single technical, human
892 or organizational failure could lead to harmful effects, and that the combinations of
893 failures that could give rise to significant harmful effects are of very low probability.
894 The independent effectiveness of the different levels of defence is a necessary element
895 of defence in depth.”.

896 3.18 The objectives of defence in depth for a nuclear installation, as stated in Ref. [23], are:

- 898 — to compensate for potential human and component failures;
- 899 — to maintain the effectiveness of the barriers by averting damage to the plant and
900 to the barriers themselves;
- 901 — to protect the public and the environment from harm in the event that these
902 barriers are not fully effective.

903 3.19 Paragraph 2.13 of SSR-2/1 (Rev. 1) [20] defines five levels of defence in depth for a
904 nuclear power plant, as follows:

906 Level 1: Prevention of deviations from normal operation and the failure of items

907 important to safety.
908 Level 2: Detection and control of deviations from normal operational states to prevent
909 anticipated operational occurrences from escalating to accident conditions.
910 Level 3: Control of accidents within the design basis.
911 Level 4: Prevention of accident progression and mitigation of the consequences of a
912 severe accident.
913 Level 5: Mitigation of the radiological consequences of radioactive releases from
914 accidents.

915
916 Recommendations from SSG-88, Design Extension Conditions and the Concept of Practical
917 Elimination in the Design of Nuclear Power Plants [24], should be addressed as well.

918
919 3.20 In preparing an application for a licence for the design of a nuclear installation, the
920 following should be verified by the licensee [or applicant](#):

- 921 (a) That suitable deterministic safety analyses for design basis accidents and design
922 extension conditions, and probabilistic safety assessments have been performed, as
923 appropriate;
924 (b) That there is adequate protection against external and internal hazards, as well as
925 adequate provision/margin against levels of natural hazards more severe than those
926 considered for design or derived from the hazard evaluation for the site;
927 (c) That there are adequate provisions for radiation protection;
928 (d) That routine radioactive discharges have been estimated and the radiological
929 consequences assessed;
930 (e) That there is evidence of learning from operating experience and programmes to evaluate
931 human and organizational factors;
932 (f) That the fundamental safety functions (i.e. (1) control of reactivity; (2) removal of heat
933 from the reactor and from the fuel store; and (3) confinement of radioactive material,
934 shielding against radiation and control of planned radioactive releases, as well as
935 limitation of accidental radioactive releases) will be fulfilled and that there is adequate
936 reliability of the associated SSCs;
937 (g) That there are adequate provisions for operational radioactive waste management;
938 (h) That adequate arrangements for decommissioning of the installation (including the
939 radioactive wastes arising from decommissioning) are in place.

940
941 The results of these verifications should be reviewed and assessed by the regulatory body when
942 considering the licence application.

943
944 3.21 Nuclear installations are required to be designed in accordance with the relevant
945 national and international codes and standards based on proven engineering practices (see
946 Requirement 9 of SSR-2/1 (Rev. 1) [20]). Requirement 13 of SSR-3 [21] and Requirement 12
947 of SSR-4 [22]).

948 3.22 Safety analyses of the design should be performed using proven codes appropriate for
949 the purpose, and should be used to specify (or improve) the following:

- 950 (a) Arrangements for commissioning of the nuclear installation;
951 (b) Categorization and classification of SSCs (in accordance with safety, quality, seismic

- 952 qualification and environmental qualification criteria);
- 953 (c) Operational limits and conditions, safety limits for items important to safety, and
954 operating procedures;
- 955 (d) Arrangements for in-service inspection, surveillance and maintenance;
- 956 (e) Arrangements for radiation protection (for workers, the public and the environment);
- 957 (f) Arrangements for emergency preparedness and response;
- 958 ~~(g)~~ Arrangements for nuclear security; ~~requirements, in accordance with national regulations~~
959 ~~and the~~
- 960 ~~(h)~~ Arrangements for international nuclear safeguards;
- 961 ~~(g)~~(i) Measures to identify interfaces between safety, security and safeguards; and to ensure
962 the consistent accomplishment of the objectives and requirements for all three areas;
- 963 ~~(h)~~(j) Human and organizational factors in the design organization;
- 964 ~~(i)~~(k) The training and certification requirements for design personnel;
- 965 ~~(j)~~(l) Documented verification and validation activities in design, testing, construction,
966 commissioning, operation, maintenance and ageing management activities to ensure that
967 the qualification of SSCs is valid for life;
- 968 ~~(k)~~(m) The programme for feedback of operating experience;
- 969 ~~(l)~~(n) Procedures for management of modifications.

970

971 3.23 The safety analyses should be reviewed, assessed and, if appropriate, challenged by the
972 regulatory body at an early stage in the licensing process. The vendor can also be involved in
973 this step, if appropriate. Additionally, the operating organization, which is required to carry out
974 an independent verification of the safety assessment before it is used by the operating
975 organization or submitted to the regulatory body, should have an internal process (which could
976 include receipt of independent advice) for review of safety analyses before submission to the
977 regulatory body to ensure that such analyses are appropriate (see Requirement 21 of GSR Part
978 4 [25]).

979 3.24 The regulatory body should, in particular, review and assess documents that form part
980 of the preliminary safety analysis report for the design of a nuclear installation, including:

- 981 (a) Safety analyses of postulated initiating events leading to anticipated operational
982 occurrences and design basis accidents, which might be caused by:
- 983 (i) External hazards (e.g. tsunamis, flooding, seismic events, volcanic eruptions,
984 aircraft crashes, tornadoes, cyclones, hurricanes, external fires, explosions of gases
985 or liquids);
- 986 (ii) Internal hazards (e.g. fire, spillages of corrosive material, internal flooding);
- 987 (iii) Internal events (e.g. mechanical failures, electrical failures, human error).
- 988 (b) Safety analyses of design extension conditions.
- 989 (c) The assumptions and approximations used in the analyses.
- 990 (d) Analyses of combinations of events.
- 991 (e) A description, identification, categorization and classification of SSCs important to safety.
- 992 (f) Operational limits and conditions, and permitted modes of operation.
- 993 (g) A list of barriers with their relative contributions to confinement of radioactive material
994 and related limits.
- 995 (h) The means by which the concept of defence in depth is applied.
- 996 (i) Planned activities for confirming safety performance.
- 997 (j) Analytical methods and computer codes used in the safety analyses and the verification
998 and validation of such codes.

999

1000 3.25 The regulatory body should ensure that the applicant or licensee has verified the
1001 adequacy of design parameters and site specific data in relation to safety criteria of the specified
1002 design basis (e.g. for protection against hazards, for cooling). In the case of a design without
1003 substantial operating experience, the applicant or licensee may have to employ additional
1004 features. These features should aim to provide enough margin to overcome uncertainties in the
1005 design due to the lack of operating experience.

1006 3.26 The applicant or licensee ~~or applicant~~ should ensure that a review of the detailed design
1007 of SSCs important to safety, as produced by designers, vendors and manufacturers, is
1008 incorporated into the management system required by GSR Part 2 [10]. The regulatory body
1009 may review, assess and inspect, as appropriate, the management processes performed by the
1010 applicant or licensee in this respect.

1011 3.27 The proposed arrangements for the safe management of radioactive waste may be
1012 included in the application for a licence for the design of a nuclear installation. The regulatory
1013 body should review, assess and inspect proposals for on-site treatment and storage of
1014 radioactive waste, including the management of spent fuel, where appropriate, to ensure that
1015 the processed waste and the waste packages will be characterized in a manner compatible with
1016 the national strategy for radioactive waste, the applicable waste acceptance criteria for
1017 subsequent steps of waste management, and regulatory requirements. Specifically, the
1018 regulatory body should satisfy itself that the waste and/or waste packages:

- 1019 (a) Will be properly characterized and compatible with the anticipated nature and duration
1020 of storage pending disposal;
1021 (b) Can be subjected to regular surveillance;
1022 (c) Can be retrieved, where necessary, for further steps of predisposal waste management;
1023 (d) Will be managed such that the volume and activity of radioactive waste are minimized;
1024 (e) Will be properly cooled and shielded, as required;
1025 ~~(e)~~(f) Will be evaluated for impact on emergency response scenarios.

1026
1027 3.28 The applicant or licensee should propose arrangements for managing radioactive
1028 discharges (liquid, and gaseous) and other discharges, including chemical and thermal
1029 discharges, as appropriate, which are expected to occur over the lifetime of the nuclear
1030 installation. The regulatory body should review, assess and inspect these proposals.
1031 Specifically, the regulatory body should satisfy itself that radioactive discharges:

- 1032 (a) Will be properly characterized and managed in compliance with regulatory requirements;
1033 (b) Can be subjected to regular surveillance;
1034 (c) Will be minimized in terms of activity and volume.

1035

1036 3.29 In addition, the licensing process should be designed to ensure that the following
1037 aspects are considered in the design of a nuclear installation:

- 1038 (a) The safe and secure transport of radioactive materials to and from the installation, and
1039 movement within the installation.
1040 (b) Safety aspects associated with the replacement of heavy and large components during the
1041 operating lifetime of the nuclear installation (e.g. steam generators, reactor pressure

- 1042 vessel head). The design should take into account:
- 1043 (i) Buried pipes and conduits;
 - 1044 (ii) Openings in structures for access to equipment;
 - 1045 (iii) Obstructions.
- 1046 (c) Access to items important to safety for:
- 1047 (i) Maintenance, inspection and testing, as appropriate;
 - 1048 (ii) Replacement;
 - 1049 (iii) Future decommissioning.
- 1050 (d) Optimization of occupational exposure when gaining access to SSCs.
- 1051 (e) The way in which the nuclear installation will be decommissioned, and how radioactive
- 1052 waste generated during operation and decommissioning will be managed, in accordance
- 1053 with national strategies.
- 1054 (f) Features for safe shutdown, including a remote shutdown facility, where appropriate.
- 1055 (g) For reactors, appropriate arrangements for storage of spent fuel (including, e.g. criteria
- 1056 for dry storage of spent fuel at reactor sites).

1057

1058 3.30 Ageing effects should be addressed in the design stage in order to identify appropriate

1059 ageing management measures for the future. This should include the actions for ensuring the

1060 integrity of the nuclear installation until the end of decommissioning.

1061 3.31 The application for a licence for design should include proposals for the certification of

1062 suppliers and contractors with functions relating to safety of the nuclear installation, and for

1063 the audit and review of the certification process. As appropriate, the regulatory body may

1064 review and assess these proposals. The regulatory body may also directly grant certificates or

1065 licences to suppliers and contractors in its own State, as appropriate, in accordance with the

1066 national regulatory framework.

1067 3.32 Before construction begins, the applicant or licensee should set up a configuration

1068 management programme⁴ for updating the design basis of the nuclear installation while

1069 ensuring that it remains in compliance with the original agreed or approved design basis.

1070 APPROVAL OF THE CONSTRUCTION OF A NUCLEAR INSTALLATION

1071 3.33 National regulations or the regulatory body should provide a clear definition of the main

1072 steps to be followed by the applicant or licensee when constructing a nuclear installation. For

1073 instance, the regulatory body may need to define a ‘site preparation’ step ~~should be defined~~;

1074 the definition of this step may vary from one State to another and may include excavation,

1075 fence erection, preparation of roads and access routes, electricity and water supply, and other

1076 infrastructure. Likewise, the regulatory body may need to define a ‘construction

1077 commencement’ step ~~should be defined~~; this step may be divided into several authorizations

1078 such as ‘first stone’, ‘construction of administrative buildings and facilities’ and ‘construction

1079 of nuclear related buildings’.

1080 3.34 Before granting an authorization or a licence for the construction of a nuclear

⁴ Configuration management is the process of identifying and documenting the characteristics of a facility’s SSCs (including computer systems and software), and of ensuring that changes to these characteristics are properly developed, assessed, approved, issued, implemented, verified, recorded and incorporated into the facility documentation [2].

1081 installation, the regulatory body should review, assess and inspect:

- 1082 (a) The management system of the applicant or licensee and vendors, as required by GSR
1083 Part 2 [10];
- 1084 (b) The site evaluation;
- 1085 (c) The items important to safety and other design features important to safety, security and
1086 safeguards;
- 1087 (d) Documentation relating to demonstration of compliance of the selected design with
1088 safety objectives and criteria, including validated results from experiments and research
1089 programmes;
- 1090 (e) A preliminary plan for emergency preparedness;
- 1091 (f) Organizational and financial arrangements for decommissioning and for management of
1092 radioactive waste and spent fuel.

1093
1094 3.35 The applicant or licensee should exercise control over the manufacture and assembly
1095 of SSCs important to safety, and this process should be reviewed, assessed and inspected, as
1096 appropriate, by the regulatory body.⁵ The processes for this control, including the control of
1097 subcontractors, suppliers and vendors, should be part of the applicant or licensee's management
1098 system.

1099 3.36 Before authorization of on-site construction, there are several conditions that should be
1100 fulfilled to ensure that this stage can proceed in a manner that will ensure safe operation of the
1101 nuclear installation. These conditions include the following and should be reviewed, assessed
1102 and inspected by the regulatory body, as appropriate:

- 1103 (a) The framework and schedule for construction and acquisition of SSCs should be
1104 adequate.
- 1105 (b) The applicant or licensee should have adequate financial and personnel capabilities.
- 1106 (c) The nuclear installation should be designed and constructed in accordance with the
1107 relevant site parameters identified by the applicant and agreed with the regulatory body,
1108 and in an adequate manner.
- 1109 (d) Planned deviations from the approved design should be fully analysed in relation to the
1110 original design intentions and submitted to the regulatory body for assessment and
1111 approval.
- 1112 (e) Nuclear security measures and emergency response (including fire protection measures)
1113 should be implemented.
- 1114 (f) Radiological monitoring equipment should be clearly specified, installed and tested
1115 before radioactive material is brought onto the site.
- 1116 (g) The applicant or licensee should conduct or update the radiological characterization of
1117 the region, and include all the material used in the construction (including samples of
1118 construction concrete) before radioactive material is brought onto the site.
- 1119 (h) Measures to comply with industrial codes, standards and rules (including conventional
1120 health and safety regulations) should be implemented before construction is started.
- 1121 (i) Regulatory control should be applied to contractors and subcontractors performing tasks
1122 relevant to SSCs important to safety.

⁵ Applicants may apply for permission to start manufacturing of long lead equipment before grant of construction license to manage the project schedule after demonstrating compliance with relevant safety requirements.

1123 (j) The interfaces with safety of any design modifications arising from the preparation for
1124 security and safeguards implementation should have been addressed.

1125 (k) Environmental monitoring equipment to monitor the impacts of on-site construction on
1126 the environment should be clearly specified, installed and tested.

1127

1128 3.37 Prior to or in the authorization of on-site construction, conditions may be imposed by
1129 the regulatory body requiring that the applicant or licensee obtains additional approvals relating
1130 to the design, construction or manufacture of certain parts of the nuclear installation. The
1131 regulatory body should also:

1132 (a) Review, assess and inspect any development of the design of the installation as
1133 demonstrated in the safety documentation submitted by the applicant or licensee, in
1134 accordance with an agreed programme (which may include requirements to improve
1135 safety through design optimization);

1136 (b) Review and assess the progress of research and development programmes relating to
1137 demonstration of the design, if applicable;

1138 (c) Review and assess the potential impact of the construction on the safe operation of any
1139 neighbouring nuclear installations or other high hazard industrial installations.

1140

1141 3.38 If part of the supply chain is in other States, the regulatory body should ensure that there
1142 are legally binding arrangements allowing the necessary access to documents and to the
1143 premises of all relevant organizations. Alternatively, such arrangements may be made part of
1144 a licence condition, for instance. If a regulatory body intends to visit premises in another State,
1145 the visiting regulatory body should inform the regulatory body of the State in which the
1146 premises are located, after approval from both States. Regulatory inspection in other States
1147 might not be possible, but it may be possible for the regulatory body to visit the premises of
1148 vendors or manufacturers in other States jointly with the regulatory body of that State.
1149 Wherever restrictions exist for joint regulatory review, it should be ensured by actual
1150 verification that the supply chain meets the necessary standards.

1151 3.39 The regulatory body should, where appropriate and under bilateral or international
1152 agreements, cooperate and exchange information and experience obtained from safety reviews,
1153 assessments and inspections with the regulatory bodies of other States that have experience in
1154 licensing the construction of one or more nuclear installations of the same design. Such
1155 cooperation should not, however, compromise the independence of the decision making
1156 process, nor should it diminish the responsibilities of a given regulatory body.

1157 3.40 Before the first nuclear material is allowed to be brought onto the site, an initial
1158 decommissioning plan, including a waste management plan, should be submitted to the
1159 regulatory body. Requirements for preparing a decommissioning plan are established in IAEA
1160 Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [26]. The
1161 decommissioning plan submitted during the construction stage of a nuclear installation should
1162 demonstrate that:

1163 (a) Sufficient funds to decommission the nuclear installation will be available at the end of
1164 operation (see Ref. [27]). This should include costs associated with spent fuel
1165 management and radioactive waste management and disposal and be based on reasonable
1166 cost estimates. The assessed liability should be estimated on the basis of the price and
1167 cost levels prevailing at the time the decommissioning plan is submitted to the regulatory

1168 body, and should be reviewed periodically. Mechanisms should be implemented for
1169 accumulating funds through the projected lifetime of the nuclear installation. In addition,
1170 provisions should be made such that appropriate funds can be made available in the event
1171 that the nuclear installation is shut down prior to the end of its planned life. As necessary,
1172 a legal framework should be established for securing decommissioning funds and for
1173 protecting them from being used for other purposes.
1174 (b) A system has been established for further development of the decommissioning plan. The
1175 plan should be reviewed periodically in the light of new techniques or information.
1176

1177 APPROVAL OF THE COMMISSIONING OF A NUCLEAR INSTALLATION

1178 3.41 Requirements for commissioning of nuclear installations are established in
1179 Requirements 25 of IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), Safety of Nuclear
1180 Power Plants: Commissioning and Operation [28], Requirement 73 of SSR-3 [21] and
1181 Requirement 54 of SSR-4 [22]. Recommendations on commissioning are provided in IAEA
1182 Safety Standards Series Nos SSG-28, Commissioning for Nuclear Power Plants [29], and SSG-
1183 80, Commissioning for Research Reactors [30].

1184 3.42 Commissioning of a nuclear installation is often divided into two main stages: (1) non-
1185 nuclear testing, which includes: individual pre-operational tests of systems and components;
1186 overall pre-operational system tests; and structural integrity tests, integrated leakage rate tests
1187 of the containment and of the primary system and secondary system; ~~commissioning before~~
1188 the introduction of radioactive material (also called ‘cold commissioning’ or ‘inactive
1189 commissioning’); and (2) nuclear testing, which includes: initial fuel loading; subcritical tests;
1190 initial criticality tests; low power tests; and power ascension tests.~~commissioning after the~~
1191 ~~introduction of radioactive material (also called ‘hot commissioning’ or ‘active~~
1192 ~~commissioning’).~~ (see Ref. [29]).

1193 3.43 Non-nuclear ~~commissioning testing~~ is performed to ensure, to the extent possible, that
1194 the nuclear installation has been constructed, and the equipment has been manufactured and
1195 installed, correctly and in accordance with the design specifications. The results of the non-
1196 nuclear ~~commissioning testing~~ should be used to inform the subsequent licensing process. If
1197 non-nuclear testing is performed at the manufacturing site, the licensing process should assess
1198 the validity of these tests once the equipment is brought and installed on the operating site.

1199 3.44 Nuclear ~~commissioning testing~~ is a major step in the licensing process performed to
1200 confirm that the nuclear installation is safe before proceeding to routine operation.
1201 Commencement of nuclear testing should normally require an authorization or additional
1202 licence from the regulatory body since it involves the introduction of radioactive material (see
1203 para. 6.3 of SSR-2/2 (Rev. 1) [28]).

1204 3.45 The applicant or licensee~~or applicant~~ should establish and justify plans and
1205 programmes for commissioning the nuclear installation. The regulatory body should conduct
1206 reviews, assessments and inspections to determine whether:

- 1207 (a) The commissioning test programme is complete and contains a set of well defined
1208 operational limits, test acceptance criteria, conditions and procedures, including the
1209 associated records;
- 1210 (b) The commissioning tests can be safely conducted as proposed by the applicant or licensee

1211 ~~or applicant~~ and their justification is appropriate;
1212 (c) Testing of SSCs may be performed at different sites.

1213
1214 3.46 There are several steps in the commissioning process for which the regulatory body
1215 may require the ~~applicant or~~ licensee to obtain prior approval and at which regulatory decisions
1216 may be made. The regulatory body should consider introducing such hold points at key steps
1217 in the commissioning programme relating to safety; for example, where it wishes to witness
1218 particular tests. The regulatory body may choose to witness these tests in the manufacturing
1219 premises, when applicable.

1220 3.47 Completed SSCs important to safety should be put into service only when they have
1221 been inspected, tested and approved by the licensee as being in accordance with the
1222 requirements set out in the design as agreed by the regulatory body.

1223 3.48 Before authorizing significant steps in the commissioning of a nuclear installation, such
1224 as the introduction of nuclear material or certain types of radioactive material, fuel loading,
1225 initial criticality or power raising, the regulatory body should complete the review, assessment
1226 and inspection of:

1227 (a) The status of the nuclear installation:

- 1228 (i) The as-built design of the nuclear installation;
- 1229 (ii) The results of non-nuclear ~~commissioning~~ testings;
- 1230 (iii) The storage facilities for nuclear material and other radioactive material.

1231 (b) Management provisions:

- 1232 (i) The management system and the programme for operation;
- 1233 (ii) The organizational structure of the operating organization, including the
1234 arrangements for ensuring training and qualification of personnel, adequate staffing
1235 levels, fitness for duty and licensing of staff for certain positions;
- 1236 (iii) The arrangements for periodic testing, maintenance and inspection;
- 1237 (iv) The organizational arrangements and procedures for dealing with modifications;
- 1238 (v) The recording and reporting systems, including those for operational data, test
1239 results, and reporting of deviations and of incidents and events;
- 1240 (vi) Management and configuration control of multiple modules on a site, if applicable.

1241 (c) Operational provisions:

- 1242 (i) The operational limits and conditions applicable during nuclear
1243 ~~testing~~ commissioning;
 - 1244 (ii) The commissioning programme and its progress;
 - 1245 (iii) The conditions under which discharges will be managed, including radioactive,
1246 chemical, thermal and other discharges, as appropriate;
 - 1247 (iv) The provisions for radiation protection;
 - 1248 (v) The provisions for fire protection;
 - 1249 (vi) The adequacy of operating instructions and procedures, especially the main
1250 administrative procedures, operating procedures for normal operation and
1251 anticipated operational occurrences, and emergency operating procedures;
 - 1252 (vii) Arrangements for emergency preparedness and response;
 - 1253 (viii) Nuclear security arrangements during commissioning;
 - 1254 (ix) Measures for accounting for and control of nuclear and radioactive material;
 - 1255 (x) Measures for meeting safeguards obligations.
- 1256

1257 3.49 There may be some overlap between the construction, commissioning and operation
1258 stages in that individual SSCs, or an entire reactor, may already be commissioned or in
1259 operation before construction of the entire nuclear installation is complete. The applicant or
1260 licensee should demonstrate that the safety case considers all potential interactions between
1261 collocated units or nuclear installations and their safety implications.

1262 3.50 As ~~nuclear~~-commissioning moves closer to completion, review, assessment and
1263 inspection by the regulatory body within the context of the licensing process should be
1264 concentrated on operational capabilities and how the nuclear installation is operated and
1265 maintained, and on the procedures for controlling and monitoring operation and for responding
1266 to deviations or other occurrences. Before authorizing routine operation, the regulatory body
1267 should review, assess and inspect the results of commissioning tests for consistency. If the
1268 regulatory body finds inconsistencies in these results, it should assess any corrections of non-
1269 conformances and modifications to the design and to operating procedures that were made as
1270 a result of commissioning. The regulatory body should review and assess any proposed changes
1271 to the operational limits and conditions.

1272 3.51 Before the start of nuclear ~~testing~~commissioning tests, staff members with functions
1273 relating to safety should be suitably trained and qualified and, where appropriate, should be
1274 licensed before being allowed to perform their functions. The regulatory body may review,
1275 inspect and license, as appropriate, during the commissioning stage and later on during
1276 operation, any organization that provides training and qualification for staff with safety related
1277 functions.

1278 3.52 The results of commissioning tests should be subject to:

- 1279 (a) Self-assessment and internal audits of the licensee. Appropriate actions and measures
1280 should be taken whenever deviations from design parameters are identified. These should
1281 be analysed by the licensee and reported to the regulatory body.
1282 (b) Review, assessment and inspection, as appropriate, by the regulatory body. The aim of
1283 these regulatory controls is to assess whether the test results are adequate for confirming
1284 the adequacy of all safety related features of the nuclear installation.

1285

1286 LICENSING OF THE OPERATION OF A NUCLEAR INSTALLATION

1287

1288 3.53 Requirements for operation of nuclear installations are established in SSR-2/2 (Rev. 1)
1289 [28], SSR-3 [21] and SSR-4 [22].

1290 3.54 Before operation of a nuclear installation is authorized or licensed, it should be
1291 demonstrated that all regulatory requirements are met, based on validation and assessment
1292 activities of operating organisation and on inspection, review and assessment by the regulatory
1293 body of:

- 1294 (a) Results of commissioning tests;
1295 (b) Operational limits and conditions;
1296 (c) Operating instructions and procedures and adequacy of staffing to implement them
1297 properly, with account taken of the need to work in shifts, when appropriate;
1298 (d) Arrangements for emergency preparedness and response;

1299 (e) The final safety analysis report.

1300

1301 3.55 Before and during operation, the person or organization responsible for the nuclear
1302 installation and its activities should demonstrate to the satisfaction of the regulatory body that
1303 it has the following:

1304 (a) Safety expectations:

1305 (i) A policy at the nuclear installation that establishes that the demands of safety take
1306 precedence over those of production;

1307 (ii) A programme for the assessment of safety performance;

1308 (iii) A mechanism for setting safety goals or targets;

1309 (iv) A programme for training in safety, security and safeguards culture.

1310 (b) Management issues:

1311 (i) A management system compliant with international standards, including a system
1312 for carrying out regular audits with independent assessors;

1313 (ii) Processes and procedures for the control of modifications to the nuclear
1314 installation, including design modifications and their implementation by graded
1315 approach;

1316 (iii) Mechanisms for configuration management for the nuclear installation and related
1317 documentation;

1318 (iv) Adequate staffing levels for the operation of the nuclear installation that take
1319 account of absences, training needs, shift work and restrictions on overtime;

1320 (v) Formal arrangements for employing and controlling contractors;

1321 (vi) A process for dealing adequately with corrective actions.

1322 (c) Competence issues:

1323 (i) Qualified staff available at all times, on duty if necessary;

1324 (ii) Systematic and validated methods for the selection of staff, including testing for
1325 aptitude, knowledge and skills;

1326 (iii) Staff training facilities and programmes;

1327 (iv) Programmes for initial, refresher and upgrade training, including the use of full
1328 scale simulators, where appropriate;

1329 (v) Guidelines on fitness for duty in relation to hours of work, health and substance
1330 abuse;

1331 (vi) Competence requirements and knowledge management for operating,
1332 maintenance, technical and managerial staff.

1333 (d) Operating experience issues:

1334 (i) Comprehensive, readily retrievable and auditable records of baseline information
1335 and operating and maintenance history;

1336 (ii) Programmes for the feedback of operating experience, including feedback of
1337 experience relating to failures in human performance;

1338 (iii) Programmes for the feedback of operating experience relevant to safety from
1339 similar nuclear installations, and from other nuclear and industrial installations;

1340 (iv) Formal procedures for event reporting.

1341

1342 3.56 Operational programmes should be established by the licensee before operation and
1343 implemented throughout the operation of the nuclear installation. The regulatory approach to
1344 reviewing, assessing and inspecting such programmes should be graded in accordance with the
1345 type of nuclear installation and its activities. Consideration should be given to shared
1346 programmes between nuclear installations and installations with multiple modules. The

1347 following programmes may be subject to approval by the regulatory body, as appropriate:

- 1348 (a) Radiation protection;
- 1349 (b) Emergency preparedness and response (on the site and off the site);
- 1350 (c) Management programmes for operations (e.g. engineering design, procurement,
- 1351 maintenance);
- 1352 (d) Fire protection;
- 1353 (e) Nuclear security;
- 1354 (f) Safeguards;
- 1355 (g) Access authorization;
- 1356 (h) Fitness for duty;
- 1357 (i) Training and qualification of licensed personnel;
- 1358 (j) Training of non-licensed staff of the installation;
- 1359 (k) Maintenance;
- 1360 (l) Initial testing of the nuclear installation and commissioning;
- 1361 (m) Pre-service inspection and testing;
- 1362 (n) In-service inspection and testing;
- 1363 (o) Surveillance;
- 1364 (p) Environmental qualification;
- 1365 (q) Design, review and implementation of modifications to the installation, procedures and
- 1366 organizational structures, as well as operation qualification and requalification after
- 1367 modifications;
- 1368 (r) Surveillance of pressure vessel material;
- 1369 (s) Testing for containment leakage;
- 1370 (t) Monitoring and sampling of effluents;
- 1371 (u) Management of spent fuel and radioactive waste;
- 1372 (v) Ageing and obsolescence management;
- 1373 (w) Environmental surveillance around the site;
- 1374 (x) Feedback of operating experience;
- 1375 (y) Nuclear safety culture.

1376

1377 3.57 The regulatory body should attach or include conditions such as the following to the
1378 operating licence, as necessary:

- 1379 (a) The person or organization responsible for the nuclear installation and its activities
1380 should not operate the nuclear installation outside the operational limits and conditions
1381 authorized or approved by the regulatory body.
- 1382 (b) The person or organization responsible for the nuclear installation and its activities
1383 should ensure that in-service inspection, surveillance and testing programmes are
1384 implemented at the nuclear installation and that such activities are performed as specified
1385 for SSCs important to safety in accordance with a time schedule, which may be subject
1386 to approval by the regulatory body, in addition to any technical safety aspects, if
1387 appropriate.
- 1388 (c) The person or organization responsible for the nuclear installation and its activities
1389 should ensure that the maintenance and ageing management programme for SSCs
1390 important to safety [accounts for results of tests mentioned in 3.57\(b\) and](#) is implemented
1391 in accordance with a time schedule, which may be subject to approval by the regulatory
1392 body.

- 1393 (d) Changes⁶, including changes to procedures, the management system, processes, SSCs,
1394 that might affect safety should be reviewed, assessed and inspected, and should be subject
1395 to internal agreement before being submitted to the regulatory body for approval, as
1396 appropriate.
- 1397 (e) The person or organization responsible for the nuclear installation and its activities
1398 should ensure that the nuclear installation is operated only under the control and
1399 supervision of duly authorized personnel in adequate numbers that are acceptable to the
1400 regulatory body.
- 1401 (f) Criteria for starting the nuclear installation after long term shutdown or module
1402 replacement.
- 1403 (g) Criteria for refuelling outages or for major maintenance programmes.
1404

1405 3.58 Before issuing an operating licence for a nuclear installation, the regulatory body should
1406 verify that:

- 1407 (a) The licensee has appropriate arrangements for reporting any deviation from normal
1408 operation to the regulatory body and for providing the regulatory body with routine reports
1409 on safety performance, adherence to regulatory requirements and efforts being made to
1410 enhance safety, as required by the regulatory body.
- 1411 (b) The licensee has a programme for analysing accessible information regarding
1412 developments and changes in regulations, procedures, documents and recommendations
1413 from organizations that collect information on experiences relevant to nuclear safety. Such
1414 information should be taken into account in operation, if appropriate.
- 1415 (c) Offsite emergency plans are in place and that offsite authorities can effectively implement
1416 public protective actions (if required) for the lifetime of the nuclear installation.
- 1417 (d) The licensee has plans for radioactive waste management and for decommissioning
1418 (including technical solutions, waste streams, the policy framework for disposal and
1419 funding), and that these will be reviewed and updated periodically during operation.

1420 3.59 Before a nuclear installation is brought back into operation following a refuelling
1421 outage, major maintenance activities, long term shutdown or other significant activities, the
1422 person or organization responsible for the nuclear installation and its activities should
1423 demonstrate to the regulatory body that the nuclear installation will be able to continue to
1424 operate in compliance with the operating licence. Resumption of operation may be subject to
1425 approval or agreement by the regulatory body, which should attach licence conditions, as
1426 appropriate.

1427 **Safety review of a nuclear installation**

1428 3.60 Over the full operating lifetime of a nuclear installation, as part of the licensing process
1429 the regulatory body should require the person or organization responsible for the nuclear
1430 installation and its activities to provide, when necessary or at appropriate intervals, evidence in

⁶ In the operation of the plant, changes in operational limits and conditions or significant safety related modifications may be necessary because of operating experience feedback, advances in nuclear technology, the need for replacement of SSCs, plant modifications proposed by the person or organization responsible for the installation and its activities, or new regulatory requirements.

1431 the form of a safety review⁷ that the installation remains fit to continue operation. The objective
1432 should be to verify:

- 1433 (a) That the nuclear installation adheres to current safety standards and national regulations;
- 1434 (b) That the licensing basis remains valid;
- 1435 (c) That any necessary safety improvements are identified;
- 1436 (d) That the required level of safety is maintained until the next safety review is due for
1437 completion;
- 1438 (e) That any measures necessary to ensure a high level of safety for the full expected
1439 operating lifetime, such as additional monitoring, are implemented;
- 1440 (f) That interfaces between safety, security and safeguards are assessed so that conflicts are
1441 minimized and any synergies are leveraged.

1442
1443 3.61 Safety reviews should be performed on a periodic basis or when requested by the
1444 regulatory body for any of the following reasons:

- 1445 (a) If there are substantial developments in safety standards and guides, practices, and
1446 analytical methods, or significant lessons learned from operating experience.
- 1447 (b) To determine the effects of ageing at the installation.
- 1448 (c) In case of major evidence of changes in external hazards or other site characteristics.
- 1449 (d) When a substantial part of the installation, such as a reactor, is replaced.
- 1450 (e) To complement routine safety assessments, which are usually limited in scope and quite
1451 specific compared with safety reviews, which offer a wider assessment of safety at the
1452 nuclear installation.
- 1453 (f) If improvements and modifications to the installation are necessary to maintain safety.
- 1454 (g) If features of the installation have a limited lifetime.
- 1455 (h) When a nuclear installation that is put into service after a prolonged period of time after
1456 testing.
- 1457 (i) To address cumulative effects of modifications and ageing at the installation, including
1458 aspects related to staffing, competence and management structures.
- 1459 (j) To address requests for extension of the operating licence. Safety reviews are a key
1460 regulatory instrument that provide reassurance that there continues to be a valid licensing
1461 basis, with respect to plant ageing and modifications implemented or needed in the light
1462 of current safety standards.
- 1463 (k) To address frequent failures of SSCs.

1464
1465 3.62 Safety reviews, whether they are periodic, requested by the regulatory body or initiated
1466 by the licensee, should be updated routinely to take account of all risks and hazards, and should
1467 be considered as 'living' from one review to another.

⁷ In many States, a systematic reassessment of safety at a nuclear installation is performed at regular intervals, typically of around ten years. This reassessment is often termed a periodic safety review, but it may be performed at any time at the request of the regulatory body when concerns about safety arise, or may be initiated by the licensee. It is recognized that in some States alternative arrangements to periodic safety reviews may be preferred. Recommendations are provided in IAEA Safety Standards Series No. SSG-25, Periodic Safety Review of Nuclear Power Plants [31].

1468 3.63 The regulatory body should ensure that such safety reviews also cover aspects which
1469 might expose workers, the public or the environment to radiation risks.

1470 3.64 In safety reviews, account should be taken by the regulatory body of:

- 1471 (a) The nature and magnitude of the potential hazards associated with the nuclear installation
1472 and its activities;
- 1473 (b) Operating experience;
- 1474 (c) Significant changes to safety or regulatory standards, criteria or objectives;
- 1475 (d) Technical developments and new safety related information from relevant sources;
- 1476 (e) Outcomes of the ageing management programme established by the licensee;
- 1477 (f) Proposed future operation timescale.

1478

1479 3.65 A detailed check of SSCs should be performed to demonstrate that the nuclear
1480 installation remains in compliance with the updated design basis. The regulatory body should
1481 review, assess and inspect this detailed review, where appropriate, to verify that the licensee
1482 has performed this review in an adequate and comprehensive manner.

1483 3.66 Where the performance of periodic safety reviews is provided for in the licensing
1484 process, the regulatory body:

- 1485 (a) Should develop requirements and guidance for the safety review process, including on
1486 the scope of the review (e.g. safety, radiation protection, emergency planning,
1487 environmental impact, time intervals, agreement on the implementation plan).
- 1488 (b) Should divide the periodic safety review into a number of tasks or ‘safety factors’ and
1489 should establish clear regulatory requirements for these tasks or factors.
- 1490 (c) Should review and assess the analysis of each safety factor performed by the licensee
1491 against current safety standards and practices.
- 1492 (d) Should agree on a basis document, developed by the licensee, that will govern the
1493 periodic safety review. This basis document should include the safety review
1494 methodology used by the licensee, the major milestones, cut-off dates, structure of the
1495 associated documents and the regulations, standards, guides, and operating practices to
1496 be used in the review.
- 1497 (e) Should review and assess, and should approve, where appropriate, corrective actions,
1498 safety improvements and good practices, determined by the licensee and submitted to the
1499 regulatory body.
- 1500 (f) Should authorize, if appropriate, the licensee’s implementation plan for the safety review.
1501 This plan should be reviewed, assessed and audited, as appropriate, before such an
1502 authorization is granted. The plan should include time schedules, to be agreed between
1503 the licensee and the regulatory body.

1504

1505 Additional information and recommendations on periodic safety reviews are provided in IAEA
1506 Safety Standards Series No. SSG-25, Periodic Safety Review of Nuclear Power Plants [31].

1507

1508 3.67 Recommendations on ageing management are provided in IAEA Safety Standards
1509 Series Nos SSG-48, Ageing Management and Development of a Programme for Long Term
1510 Operation of Nuclear Power Plants [32], and SSG-10 (Rev. 1), Ageing Management for
1511 Research Reactors [33]. Ageing management plays a central role in the periodic safety review.
1512 As part of the licensing process, the regulatory body should verify the existence of an ageing

1513 management programme. There are certain essential elements of ageing management, and
1514 these should be considered by the regulatory body in assessing the licensee's safety analyses.
1515 Such essential elements include:

- 1516 (a) An understanding of the installation's design basis;
- 1517 (b) A rigorous programme for equipment qualification (for design, construction and
1518 modifications);
- 1519 (c) Identification of actual service conditions (actions to be taken during the design,
1520 construction, commissioning and operation stages);
- 1521 (d) An understanding of material properties and possible ageing mechanisms;
- 1522 (e) Identification of mechanical and thermal loadings;
- 1523 (f) A knowledge of the ageing of SSCs due to physical and chemical processes, or due to
1524 SSCs becoming out of date or obsolete due to knowledge and technology evolution, the
1525 associated changes in codes and standards or ageing of human skills, knowledge,
1526 competence;
- 1527 (g) A systematic ageing management programme.

1528

1529 3.68 After review, assessment and inspection, depending on national regulations and the
1530 outcome of the safety review, the regulatory body may decide to renew, amend, suspend or
1531 revoke the operating licence for the nuclear installation and its activities.

1532 **Long term shutdown of a nuclear installation**

1533 3.69 The licensee should submit to the regulatory body for authorization the specifications
1534 for maintaining the safety, security and safeguards needs of the nuclear installation during long
1535 term shutdown⁸. The regulatory body should review, assess and inspect such specifications and
1536 may attach conditions.

1537 3.70 Long term shutdown should be justified by the licensee, and related plans and
1538 programmes should be subject to agreement by the regulatory body. Long term shutdown needs
1539 to be managed in a safe manner by the person or organization responsible for the nuclear
1540 installation and its activities, and should be subject to regulatory control, especially regarding:
1541 waste storage, spent fuel management, fire protection and suppression, radiation protection and
1542 fulfilment of safety functions. During long term shutdown, a safety review should also be
1543 performed to help maintain safety.

1544 3.71 If a nuclear installation has been shut down for a long period, before it is returned to
1545 operation the regulatory body may require the licensee to perform a safety review and to re-
1546 engage with the licensing process, as appropriate.

1547 **Post-operational activities**

1548 3.72 At the end of its operating lifetime, the nuclear installation should enter a phase of post-
1549 operational decontamination and reduction of hazards to move towards a more passively safe
1550 state. Post-operational activities could be carried out under the current operating licence or the

⁸ Long term shutdown is a state that is different from refuelling outage, maintenance, inspection or refurbishment, during which the nuclear installation is not in operation (e.g., a nuclear installation may be in long term shutdown just before its decommissioning, or for economic, political and other reasons).

1551 decommissioning licence. Radiation protection considerations may necessitate that certain
1552 activities are delayed to allow radioactivity to decay and radiation exposures to be reduced. To
1553 facilitate this process, some activities relevant to decommissioning (see paras 3.74–3.86) may
1554 be performed after shutdown of the nuclear installation under licence provisions carried over
1555 from the operating stage. Such activities include:

- 1556 (a) Management of operational waste;
- 1557 (b) Measurements to determine the inventory of radioactive material;
- 1558 (c) Removal of nuclear fuel;
- 1559 (d) Post-operational decontamination and reduction of hazards (including removal of liquids,
1560 materials relating to the original operation and other mobile hazardous materials for
1561 disposal or safe storage).

1562

1563 3.73 After post-operational decontamination and removal of hazards, safe storage or
1564 enclosure ('mothballing') and interim storage may be permitted; for example, to allow for
1565 radioactive decay.

1566 APPROVAL OF THE DECOMMISSIONING OF A NUCLEAR INSTALLATION

1567

1568 3.74 Requirements for decommissioning⁹ of facilities are established in GSR Part 6 [26],
1569 and supporting recommendations for nuclear installations are provided in IAEA Safety
1570 Standards Series No. SSG-47, Decommissioning of Nuclear Power Plants, Research Reactors,
1571 and Other Nuclear Fuel Cycle Facilities [34]. Information on the transition from operation to
1572 decommissioning is provided in Ref. [35].

1573 3.75 An updated, detailed final decommissioning plan and its supporting safety assessment
1574 is required to be submitted by the licensee to the regulatory body for approval, prior to
1575 commencement of decommissioning activities (see Requirement 11 of GSR Part 6 [26]).

1576 3.76 The decommissioning stage consists of one or more substages, which may be subject
1577 to separate regulatory approval or authorization. Different human resources and competences
1578 to those during operation are needed for decommissioning. Furthermore, staff motivation is
1579 crucial to maintaining a strong safety culture in an installation that is undergoing
1580 decommissioning.

1581 3.77 The nuclear installation should remain licensed throughout the period of
1582 decommissioning, with appropriate control retained by the licensee and with appropriate
1583 oversight by the regulatory body.

1584 3.78 Decommissioning should only be authorized after the safe management of radioactive
1585 waste has been demonstrated in a waste management strategy that is part of the
1586 decommissioning plan. Large volumes of radioactive waste may be generated in a short time,
1587 and the waste may vary greatly in type and activity. In the review, assessment and inspection
1588 of the decommissioning plan by the regulatory body, it should be verified that radioactive waste

⁹ Decommissioning comprises: the preparation and approval of a detailed decommissioning plan; the actual decommissioning activities; the management of waste arising from these activities; demonstration that the decommissioning end point is achieved; and the updating of all existing safety related documents, as appropriate, including documents on nuclear security and emergency response, safeguards, and the plan for cleanup of the site.

1589 can be managed safely through existing and, as necessary, new transportation routes.

1590 3.79 Requirements for radioactive waste management are established in IAEA Safety
1591 Standards Series Nos GSR Part 5, Predisposal Management of Radioactive Waste [36], and
1592 SSR-5, Disposal of Radioactive Waste [37].

1593 3.80 As part of the licensing process for a nuclear installation, the decommissioning plan
1594 should be reviewed, assessed and inspected by the regulatory body to verify that
1595 decommissioning activities can be accomplished safely with a progressive and systematic
1596 reduction of radiological hazards (further recommendations can be found in SSG-90, Radiation
1597 Protection Aspects of Design for Nuclear Power Plants [38]). The decommissioning plan is
1598 required to include the selected decommissioning strategy; the schedule, type and sequence of
1599 decommissioning actions; the waste management strategy; and the proposed end state for the
1600 nuclear installation (see para. 7.10 of GSR Part 6 [26]). The decommissioning plan should also
1601 specify the requirements for on-site and off-site monitoring, as well as for nuclear security and
1602 surveillance during decommissioning.

1603 3.81 The progressive and definitive shutdown of SSCs important to safety should be
1604 adequately planned and managed by the licensee, and the regulatory body should review, assess
1605 and inspect for approval this shutdown or parts thereof, as appropriate, as part of the licensing
1606 process.

1607 3.82 In authorizing the decommissioning of a nuclear installation, the regulatory body
1608 should take particular care in specifying measures to ensure the licensee's compliance with
1609 licence conditions (i.e. because the sanction of stopping activities at the nuclear installation or
1610 revoking the licence might not be effective at this stage).

1611 3.83 In situations where off-site decommissioning is considered (see Appendix II para.
1612 II.15), the regulatory body should ensure specific licence conditions are included to address
1613 this.

1614 3.84 Where it is proposed to defer dismantling in whole or in part (see para. 1.9 of GSR Part
1615 6 [26]), it should be demonstrated that there will be no undue burden on future generations and
1616 that the benefits outweigh immediate dismantling. Deferral of dismantling should be justified
1617 on a case-by-case basis to the regulatory body. For example, proposals for deferral of
1618 dismantling should address:

1619 (a) Care and maintenance of the nuclear installation during the deferral period;
1620 (b) Identification of ageing mechanisms;
1621 (c) Knowledge management, including expected loss of staff and expertise.
1622

1623 3.85 In dismantling a nuclear installation, activities such as decontamination, cutting and
1624 handling of large equipment, and the progressive dismantling or removal of some existing
1625 safety systems have the potential to create new hazards. The safety analyses for the nuclear
1626 installation should therefore be reviewed and updated as dismantling progresses. In particular,
1627 in reviewing an application for a licence for decommissioning, the regulatory body should
1628 consider the following aspects during the decommissioning stage:

- 1629 (a) Waste storage;
1630 (b) Spent fuel management;
1631 (c) Fire protection and suppression;
1632 (d) Radiation exposure of workers, the public and the environment;
1633 (e) Movement of radioactive material on-site and off-site;
1634 (f) Non-radiological hazards, which should be dealt with by coordinated activities between
1635 the relevant regulatory authorities under clear memoranda of understanding;
1636 (g) Integrity of vessels and systems for preventing leakage;
1637 (h) Supply systems to prevent failure and to maintain the installation under proper control
1638 (e.g. electricity supply, ventilation);
1639 (i) Integrity of hoisting devices to prevent falling of loads;
1640 (j) Emergency preparedness and response plans.

1641
1642 3.86 A final decommissioning report is required to be prepared, supported by appropriate
1643 records, and should be submitted to the regulatory body (see para. 9.1 of GSR Part 6 [26] and
1644 Annex II of SSG-47 [34]).

1645
1646 **RELEASE OF A NUCLEAR INSTALLATION FROM REGULATORY CONTROL**

1647
1648 3.87 The release of a nuclear installation or a site from regulatory control requires, among
1649 other things, completion of decontamination and dismantling and removal of radioactive
1650 material, radioactive waste and spent fuel and contaminated structures and components (see
1651 paras 1.8 and 9.2 of GSR Part 6 [26] and IAEA Safety Standards Series No. WS-G-5.1, Release
1652 of Sites from Regulatory Control on Termination of Practices [39]). If spent fuel storage
1653 facilities or radioactive waste storage facilities remain on the site after the end of
1654 decommissioning, they should be licensed as new operating facilities (see para 6.15 of SSG-
1655 47 [34]) .

1656 3.88 The regulatory body should provide guidance on radiological criteria for the removal
1657 of regulatory controls over the decommissioned nuclear installation and the site and should
1658 ensure that an adequate system is implemented for properly managing this removal.

1659 3.89 Before a nuclear installation is released from regulatory control, the regulatory body
1660 should review, assess and inspect the evidence for the following:

- 1661 (a) That all responsibilities covered by all authorizations have been satisfactorily discharged
1662 by the licensee and that there is no reasonable expectation that the licensee will have
1663 further responsibilities with respect to anything remaining on the site;
1664 (b) That any necessary institutional controls, including continuing environmental
1665 monitoring, are implemented;
1666 (c) That the final radiological status of the nuclear installation is fully documented;
1667 (d) That the radiological history of workers (including contractors) is fully documented;
1668 (e) That documentation is made publicly available (unless protected by law from disclosure,
1669 such as nominative dose records).

1670
1671 3.90 Before termination of the licence and release of the site from regulatory control, a final
1672 radiological survey is required to be performed by the licensee (see para. 3.4 of GSR Part 6
1673 [26]). The survey is to be conducted at the completion of the decommissioning activities and

1674 should be examined by the regulatory body to verify that the regulatory criteria and
1675 decommissioning objectives have been fulfilled. The results of the survey should be archived
1676 and kept for a suitable period, as appropriate.

1677 3.91 Once the regulatory body has accepted the evidence provided, the licence can be
1678 terminated and the licensee can be relieved of further licensing responsibilities.

Appendix I

EXAMPLES OF DOCUMENTS TO BE SUBMITTED TO THE REGULATORY BODY

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I.1 ~~The following are examples of documents that may be updated by the applicant or licensee and submitted to the regulatory body. As requested by the regulatory body, the following documents should be developed and updated by the applicant or licensee, as appropriate, and submitted to the regulatory body.~~ during the licensing process. The content of these documents may be divided or combined into different documents, as appropriate:

- (a) A descriptive construction report (including a quality manual), which consists of a description of the nuclear installation, the process and technologies used, justification of related activities and considerations for decommissioning;
- (b) References to, and benchmarks against, other relevant nuclear installations, including those in other States, if any, and a summary of the most significant differences between the installations;
- (c) A preliminary plan for the project, including phases and the anticipated schedule (including technical research and development, if necessary);
- (d) A prior economic study regarding the necessary financial investments and the expected costs;
- (e) A site evaluation report, including a report on environmental radiation monitoring ~~(see paras 3.3–3.10)~~;
- (f) Reports on the use of cooling sources;
- (g) The environmental impact assessment and reports on discharges into the environment;
- (h) The strategy and plans for public involvement in the licensing process;
- (i) A report on the management and organization of the design and construction project, including responsibilities and a list of contractors;
- (j) A report on the acquisition programme, including a list of the SSCs and their origin, and, as applicable, details of the manufacturing process for SSCs important to safety;
- (k) The strategic plan for the licensing process, including the set of requirements, guides, codes and standards to comply with, which may be partly adopted from the vendor State (if any);
- (l) A preliminary safety analysis report before authorization to begin construction, which may include information on site evaluation, the design basis, nuclear and radiation safety, deterministic analyses and complementary probabilistic safety assessment;
- (m) The preliminary plans relating to the operating organization and the application of its management system to all licensing steps;
- (n) Technical design documents;
- (o) Nuclear security plans prepared using national design basis threat or representative threat statement, and especially interfaces with safety measures;
- (p) Fire protection plans;
- (q) Plans for accounting and control of nuclear material;
- (r) Training and qualification plans for operating personnel;
- (s) Proof of trustworthiness of all staff who will be engaged in responsible or sensitive positions;
- (t) Commissioning programmes and reports ~~(see paras 3.41–3.52)~~;
- (u) Final safety analysis reports on the site evaluation, design, construction, commissioning and operation stages and on provisions for decommissioning;

- 1726 (v) Ageing management plans;
- 1727 (w) General operating rules and operating procedures ~~(see paras 3.53–3.72)~~;
- 1728 (x) Technical specifications, including operational limits and conditions;
- 1729 (y) A plan for collecting and applying feedback from operating experience;
- 1730 (z) Plans for evaluating and improving safety performance;
- 1731 (aa) Emergency operating procedures and severe accident management guidelines;
- 1732 (bb) Emergency preparedness and response plan;
- 1733 (cc) The radiation protection programme and associated reports;
- 1734 (dd) Reports on radioactive waste and spent fuel management, including proposals for
1735 treatment, packaging, storage and final disposal of waste (including decommissioning
1736 wastes) and a description of the system for the classification and characterization of
1737 waste, and rules and criteria to release waste;
- 1738 (ee) An indicative list or detailed inventory of sources;
- 1739 (ff) Modification rules (may be included in the general operating rules);
- 1740 (gg) Details of the maintenance programme and the periodic testing programme;
- 1741 (hh) Reports of periodic safety reviews or other safety reviews;
- 1742 (ii) Decommissioning plans and reports, including details of final shutdown, and
1743 decommissioning substages, actions and safety analyses.

Appendix II

LICENSING OF SMALL MODULAR REACTORS

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II.1 The characteristics of small modular reactors and their associated deployment models¹⁰ introduce some differences compared to those of land-based large nuclear power plants [6], ranging from factory manufacturing and testing to factory construction, and new programmes for maintenance and decommissioning. The licensing process of small modular reactors may also involve additional safety and regulatory considerations, particularly for those reactors that are constructed, commissioned, or decommissioned away from the site. However, it should be recognized that those stages such as siting, design, construction, commissioning, operation and decommissioning are six major stages of the lifetime of a nuclear installation and of the associated licensing process (see Ref. [2]), and a small modular reactor should also follow this basic stage during its lifetime. For examples of differences, the following list shows the potential stages of the lifetime of a small modular reactor, noting that each of these stages might not be needed for all small modular reactor designs:

- 1759 (a) Siting and site evaluation;
1760 (b) Design;
1761 (c) Off-site construction or manufacturing;
1762 (d) Off-site commissioning;
1763 (e) Transport (both to and from facility);
1764 (f) On-site construction;
1765 (g) On-site commissioning;
1766 (h) Operation;
1767 (i) On-site decommissioning;
1768 (j) Off-site decommissioning;
1769 (k) Release from regulatory control.

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Some of these are new stages that are not relevant to land-based large nuclear power plants. The new stages may have an impact on how the licensing process is conducted for a small modular reactor. For example, the licensing of such a reactor may include new hold points.

1774 II.2 The recommendations in this Safety Guide are generally applicable to small modular
1775 reactors. This appendix highlights the potential impact of the new deployment models for small
1776 modular reactors on the licensing process and provides additional considerations to ensure that
1777 regulatory bodies are able to license different types of nuclear installation and have adequate
1778 capabilities and resources for their regulatory activities.

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CAPACITY OF THE LICENSEE OF A SMALL MODULAR REACTOR TO FULFIL ITS RESPONSIBILITIES

Influence from external stakeholders in relation to small modular reactors

1783 II.3 Commercial arrangements may be made between various stakeholders involved in the
1784 deployment of a small modular reactor, for example for establishing energy production projects
1785 (electricity, heat, hydrogen) or industrial applications. These arrangements can lead to one or

¹⁰ In this Safety Guide, deployment model refers to the features of a project that determine where and when it will be deployed. It also includes aspects related to how the project is managed.

1786 more organizations of the different stages of development of a small modular reactor. The
1787 regulatory body should hold a single licensee responsible for safety for all stages of the lifetime
1788 of the reactor regardless of commercial arrangements. The regulatory body should seek
1789 assurances on this licensee's organizational capability to effectively oversee safety
1790 considerations at all stages of the lifetime of the small modular reactor.

1791 II.4 To fulfil its responsibilities, a licensee is required to give an overriding priority to safety.
1792 Consequently, licensees should make provisions in terms of organization and funding to ensure
1793 it meets its obligations regarding any decision that can impact safety in the short and in the
1794 long term.

1795 II.5 The regulatory body should assess the ways in which external stakeholders could
1796 influence licensees in the conduct of their licensed activities to ensure that the licensee will be
1797 able to exercise its responsibility without undue interference from commercial stakeholders.
1798 This may include assessing the interfaces between organizations (licensee, neighbouring
1799 entities, shareholders) to evaluate how arrangements can impact the licensee.

1800 **Licence transfer for small modular reactors**

1801 II.6 During the lifetime of a small modular reactor, for some designs, the licence may be
1802 transferred from one organization to another, but any transfer of licenses should not impact the
1803 basic licensing process. The regulatory body should ensure that there is a process for a licence
1804 transfer in which the regulatory body ensures the new licensee is capable of maintaining safety,
1805 as well as the arrangements for nuclear security and safeguards. For example:

- 1806 (a) An application by the recipient organization should be submitted to the regulatory body
1807 and should demonstrate the applicant's capability and capacity to meet regulatory
1808 requirements. This includes any proposals of significant changes in the licensed
1809 activities.
- 1810 (b) An application should demonstrate adequate provisions will be implemented to maintain
1811 safety, security, and safeguards and identify the responsibilities of both the foregoing
1812 licensee and the applicant.

1814 **Reliance on contractors and capacity for oversight of small modular reactors**

1815 II.7 Deployment models for small modular reactors may include an increase in outsourced
1816 activities, such as plant operations, remote monitoring, refuelling, maintenance, and
1817 configuration management between similar installations. Licensees might outsource these
1818 types of activity to contractors to perform a wide range of specialized activities or all
1819 maintenance activities across many sites.

1820 II.8 When the licensee is outsourcing activities, the regulatory body should verify that the
1821 licensee will maintain:

- 1822 (a) Proper and adequate oversight of all activities;
- 1823 (b) An informed customer capability [2] for the activities being undertaken;
- 1824 (c) Configuration management, which includes personnel access to applicable configuration
1825 management documentation;
- 1826 (d) Adequate quality management of activities;
- 1827 (e) Prime responsibility for safety of the nuclear installation(s);
- 1828 (f) A commitment to fostering a strong safety culture;
- 1829 (g) Technical knowledge and skills within the licensee organization;

1830 (h) Proper interface mechanisms and procedures for any activities that are outsourced to
1831 several contractors.

1832

1833 II.9 The licensing process should include provisions to ensure that the licensee maintains
1834 independence and the ability to perform their obligations.

1835

1836 SITING A SMALL MODULAR REACTOR NEAR AN INDUSTRIAL SITE OR
1837 POPULATION CENTRE

1838 II.10 Requirements for site evaluation are established in SSR-1 [17]. A small modular reactor
1839 can be used for purposes other than electricity production, such as heat production for district
1840 heating or industry, hydrogen production or desalination. This may involve installing reactors
1841 near another industrial site or a population centre. In some cases, part of the nuclear installation
1842 might have an interface with the neighbouring industrial site and be separated by a single
1843 barrier (e.g. a heat exchanger). In such cases:

1844 (a) Deployment of a small modular reactor near an industrial site may need additional
1845 planning and coordination to ensure that:

1846 (i) There are adequate arrangements for emergency preparedness and response;

1847 (ii) Any activities or changes to activities in the adjacent installation, with direct
1848 relation to the small modular reactor (e.g. increase in power demand, modification
1849 of electrical power supply) or in any other nearby installation, do not negatively
1850 impact reactor safety;

1851 (iii) Major activities at the industrial site, such as heavy lifting, blasting or excavation
1852 do not negatively impact reactor safety;

1853 (iv) Where systems are shared between the small modular reactor and the adjacent
1854 installation, their operation and any change/modification should be closely
1855 followed as part of the small modular reactor's operation to maintain the capability
1856 to perform their functions under all conditions;

1857 (v) Radiological impact to the population and environment is reduced as much as
1858 possible.

1859 (b) The site boundaries of the small modular reactor should be defined and based on safety,
1860 security, and safeguards considerations.

1861 (c) The licensee should demonstrate that site-based infrastructure supports safety, security,
1862 safeguards as part of the overall licensing activity.

1863 (d) For commonalities, such as security, emergency preparedness and response, and accident
1864 management, coordination among the licensee, the end user, and other stakeholders
1865 should be implemented.

1866 (e) When deploying a small modular reactor near a population centre (e.g. to provide district
1867 heating), the licensee is also required to assess the impact of an emergency on the
1868 surrounding population and environment. Size, technology, location, and possible
1869 underground siting of the installation, along with remoteness of the community might
1870 affect the impact significantly.

1871

1872 DEPLOYMENT OF MULTIPLE SMALL MODULAR REACTORS

1873 **Standardized fleet deployment for small modular reactors**

- 1874 II.11 Possible approaches to fleet deployment¹¹ of small modular reactors include:
- 1875 (a) A ‘certified design’ model, where a reactor design is certified by a regulatory body or
1876 jointly by several regulatory bodies. Once a design is certified, licensing efforts then
1877 focus on site-specific aspects and any changes to the certified design.
- 1878 (b) A deployment model where the design may be modified from one plant to the next. For
1879 this model the regulatory body should review the first-of-a-kind reactor at the same level
1880 of assessment as the certified design described in II.11(a), and then its efforts will focus
1881 on the differences from one plant to the next for both the design and site-specific aspects.
1882
- 1883 II.12 When reviewing a licensing application of a reactor that is part of a fleet, the regulatory
1884 body could consider focusing their review efforts on the differences from one plant to the next.
- 1885 II.13 For a licence application of a reactor that is part of a fleet, the applicant should
1886 demonstrate that proper configuration management processes are established to track changes
1887 in each plant as well as differences between plants.
- 1888 **Multiple units/reactor modules or replacement of major components of a small modular**
1889 **reactor at a single site**
- 1890 II.14 Some deployment models for small modular reactors could allow for different reactor
1891 types or the addition or replacement of reactor units or reactor modules ([see IAEA TECDOC-](#)
1892 [1936, Applicability of Design Safety Requirements to Small Modular Reactor Technologies](#)
1893 [Intended for Near Term Deployment](#) [40]) or major components or systems at various times
1894 throughout the lifetime of the facility. ~~This may include replacing the entire reactor module~~
1895 ~~when the fuel is spent; replacing an entire reactor assembly, or replacing the entire facility.~~
1896 Additional units/reactor modules may be in close proximity to or sharing the same
1897 infrastructure as operating reactor modules (See para 3.9(a)(iii) for additional information on
1898 multiple nuclear installations on the same site.). The potential for evolution of design over time
1899 could mean differences among the reactor modules installed at a single facility. As such:
- 1900 (a) The licensing process should consider the number of reactor modules that could be
1901 present at the site simultaneously and operated over the lifetime of the facility.
- 1902 (b) A licensing activity that considers multiple reactor modules of essentially the same
1903 design at a facility may undergo a single review and safety evaluation by the regulatory
1904 body in the case when these reactor modules are licensed at the same time. If the timing
1905 of licensing is different, additional considerations may be needed.
- 1906 (c) When different reactor designs are proposed for a single site, separate licenses should be
1907 necessary for each reactor design because of the likelihood of significant differences in
1908 construction, commissioning, operation, maintenance and decommissioning introduced
1909 by the design.
- 1910 (d) The licensing process should consider the possibility of incrementally bringing reactor
1911 modules/units into and out of service as well as the replacement of reactor modules. This
1912 should include how construction, commissioning, operation, and decommissioning of a
1913 reactor module might impact the other reactor modules. Even in these occasions,
1914 fundamental safety function of remaining individual reactors is required to be maintained
1915 with their own items important to safety.
- 1916 (e) If an entire reactor module ~~or reactor assembly~~ is being replaced, the licensee should

¹¹ For the purposes of this appendix, fleet deployment is the deployment of multiple small modular reactors of the same or similar design. Fleet deployment aims to minimize the design changes between reactors in the same fleet.

- 1917 demonstrate that the new components and systems are within the licensing basis of the
1918 small modular reactor. This may involve off-site assessment of replacement components.
1919 Alternatively, the licensee may need to obtain a new licence for the replacement.
- 1920 (f) The licensee should describe their programmes and processes that control how activities
1921 for multiple units and configuration differences will be managed. The impact of any
1922 reactor design changes should be well understood, documented, and accounted for.
- 1923 (g) The licensing process should consider the impact of common aspects at the site, such as
1924 environmental review, emergency response plans, security, and safeguards.
- 1925 (h) The licensee should implement an emergency plan for the entire site. The licensee should
1926 ensure that processes are implemented so that shared personnel or services are available
1927 when needed for safety or security or emergency reasons.

1928

1929 RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT

1930 II.15 SMR operations are expected to result in the generation of a wide range of radioactive
1931 wastes and spent fuels, influenced by the interaction of the fuel system (e.g., fuel composition,
1932 shape, enrichment, and assembly form), moderator (for thermal reactors), and coolant selection
1933 [6]. Consequently, it is important that the regulatory body, during the licensing process, reviews
1934 and assesses the facility's safety measures for the predisposal management of all radioactive
1935 waste types, including spent fuel, arising from commissioning, operation, and
1936 decommissioning of an SMR facility. In this licensing context, the following key areas are
1937 recommended for safety considerations in radioactive waste and spent fuel management:

- 1938 (a) The design of the SMR facility(ies) should provide means and consideration (i.e. material
1939 selection, modularity construction) for minimization of radioactive waste generation (by
1940 volume and activity).
- 1941 (b) The SMR facilities should have an on-site radioactive waste management system capable
1942 of characterization, pretreatment, treatment, and storage of radioactive waste (solid,
1943 liquid, and gaseous) throughout commissioning, operation, and decommissioning. The
1944 system should be designed for handling radioactive waste streams from normal
1945 operations, anticipated operational occurrences and accident conditions.
- 1946 (c) The types and quantities of radioactive waste and spent fuel should be specified, to allow
1947 review and assessment by the regulatory body within the licensing process.
- 1948 (d) The annual volume of radioactive waste generated, and the capabilities needed to manage
1949 it during SMR operation and future disposal should be determined, preferably during the
1950 design phase and through licensing application.
- 1951 (e) System requirements for spent fuel management (cooling times, wet/dry storage
1952 capacity, as applicable) at the SMR facility should be clearly defined, including the
1953 expected annual generation of spent fuel quantities.
- 1954 (f) The facility effluents released due to commissioning and operation should be identified
1955 and quantified. The radioactive waste management system should have sufficient
1956 capacity to manage effluents during normal operations, anticipated operational
1957 occurrences and accident conditions.
- 1958 (g) The proximity of SMRs to industrial sites or large population areas should be assessed
1959 to ensure safety throughout decommissioning.
- 1960 (h) The design should ensure that spent fuel and radioactive waste generated during the
1961 facility's lifetime are storable and disposable. Disposal routes for spent fuel and
1962 radioactive waste should be identified and feasible within the Member State's national
1963 strategy.
- 1964 (i) Options for interim storage of spent fuel on-site should be evaluated.
- 1965 (j) Transportation requirements for moving radioactive waste and spent fuel off-site should

1966 be established.
1967 (k) Existing disposal solutions for radioactive waste, including spent fuel, should be assessed
1968 for suitability to the waste expected from SMRs.
1969

1970 II.16 Many of the safety considerations applied to the licensing processes for traditional
1971 nuclear power plants are also applicable to the licensing of SMRs. However, key areas of
1972 novelty in the review process include the modularity of reactor units within the same facility,
1973 the proximity to industrial zones or large population areas, and the unique waste streams and
1974 spent fuel associated with non-light water SMRs.

1975 II.17 At the time of writing this Appendix, Member States have limited experience with the
1976 licensing, construction, operation, or decommissioning of SMR facilities. While some
1977 experimental facilities are operational or in various stages of design and construction, broader
1978 experience in commissioning, operating, and decommissioning SMR power plants is needed.
1979 Member States are therefore encouraged to share with one another the early experiences gained
1980 in novel areas.

1981 OFF-SITE CONSTRUCTION, COMMISSIONING, AND DECOMMISSIONING

1982 H.15II.18 Some deployment models for small modular reactors propose to perform some
1983 of the manufacturing, assembly, and commissioning activities at the manufacturing site,
1984 possibly prior to the identification of an operating licensee. Some deployment models also
1985 propose off-site decommissioning. For such cases:

- 1986 (a) The off-site facilities and locations where activities such as fuel loading, nuclear testing,
1987 or decommissioning of a reactor module are performed should be licensed.
- 1988 (b) The regulatory body should review, assess, and inspect licensee provisions for the
1989 oversight of activities important to safety, including those performed off the site. These
1990 provisions, as well as the regulatory body's oversight, should follow a graded approach,
1991 that is they should be proportionate to the safety significance of the systems being
1992 manufactured, assembled, and tested off the site. The regulatory body should apply the
1993 same level of practices on review, assessment and inspection to small modular reactor as
1994 those of large power reactors, with some consideration of the configuration of reactors.
- 1995 (c) The regulatory body should be able to assess the way safety related activities are
1996 conducted, including those performed off the site. This may be achieved by direct
1997 oversight of manufacturing sites through qualification, certification, or licensing of the
1998 off-site facility or activity, or review of the same carried out by a regulatory body in
1999 another State. This may also be achieved through the oversight of the licensee's
2000 management system of its supply chain.
- 2001 (d) The licensee should maintain thorough and traceable documentation of inspections, tests,
2002 analyses, and acceptance criteria of activities important to safety, to demonstrate that
2003 these activities meet the expectations from the safety case. This may need to be ensured
2004 by the vendor or the manufacturer, as these activities could be performed in the absence
2005 of a licensee. The specific mechanisms of control of the manufacturing and construction
2006 activities in the absence of a licensee are out of scope for this document.
- 2007 (e) The potential effects of transport of manufactured and/or assembled SSCs on their quality
2008 and qualification and the validity of the tests performed off the site should be assessed in
2009 the licensing process.
- 2010 (f) The licensing process for transportable nuclear power plants should ensure there are
2011 adequate provisions for testing before and after transport of a reactor module to the
2012 deployment site.

- 2013 (g) The regulatory body should ensure that the licensee provides sufficient information in
2014 the licence application to ensure that the facility can be safely decommissioned (i.e.
2015 appropriate material selection to reduce neutron activation, generation of complex
2016 radioactive waste during operation, the modular design to enable use of well-established
2017 dismantling technologies, etc.).
2018 (h) The regulatory body should ensure that under the proposed decommissioning strategy,
2019 there is sufficient funding (accrued during the operation of the SMR facility) to complete
2020 the decommissioning project and for the site to be released. Unrestricted release of sites
2021 from regulatory control should be the primary objective.
2022 -

2024 SHARING AND LEVERAGING INFORMATION ON SMALL MODULAR REACTORS

2025 H.16II.19 As small modular reactors are expected to deploy more standardized designs
2026 worldwide, collaboration amongst regulatory bodies in different States may be necessary and
2027 regulatory bodies may choose to leverage work that has already been performed in another
2028 State. In addition, with reactor lifetimes projected to be many decades, it can be assumed that
2029 design changes will be needed over the reactor lifetime to cover, for example, improvements
2030 or changes in design due to operating experience, as well as changes needed to support
2031 obsolescence of components (e.g. instrumentation and controls). As such, States need to be
2032 able to ensure they properly understand and document how leveraged information was used in
2033 their decision making process, and also ensure that their documentation is done with enough
2034 detail that regulatory oversight capability can be maintained~~are capable of regulatory oversight~~
2035 over the lifetime of the facility.

2036 H.17II.20 When leveraging information from other regulatory bodies, the regulatory body
2037 receiving information should have full access to the design details and background information
2038 to make regulatory decisions and should validate the information received.

2039 H.18II.21 When considering the use of information from other regulatory bodies, the
2040 regulatory body receiving information should ensure that it:

- 2041 (a) Understands the information (i.e., maintains an informed customer capability [2]);
2042 (b) Understands what the information was previously assessed against and what it will be
2043 subsequently assessed against (i.e. what regulations, policies, and safety standards the
2044 original assessment was performed against);
2045 (c) Takes responsibility for its own regulatory decisions.

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