



# Report Rappo

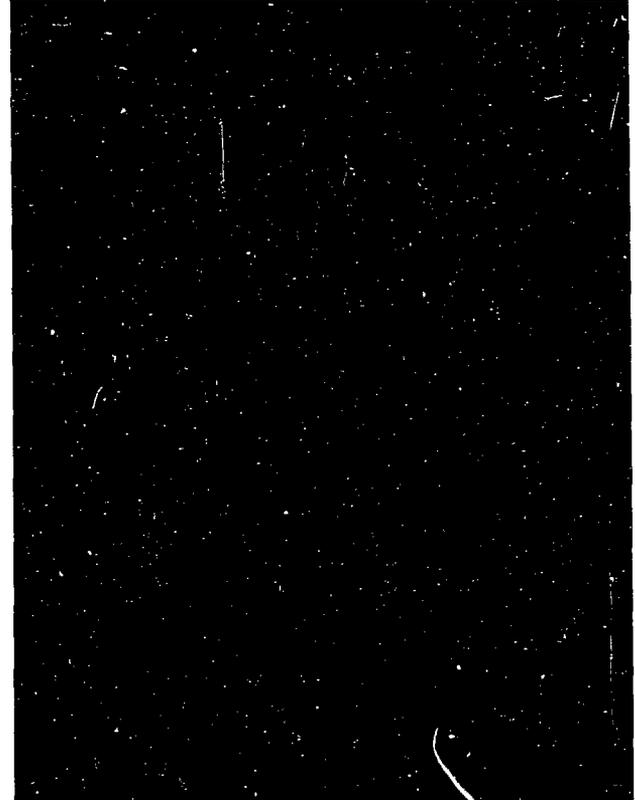
INFO 0043



Atomic Energy  
Control Board

Commission de contrôle  
de l'énergie atomique

C A 3205531



THE DEVELOPMENT OF AECB  
REGULATORY DOCUMENTS

by

M. Joyce

Atomic Energy Control Board  
Ottawa, Canada

April 28, 1981

THE DEVELOPMENT OF AECS  
REGULATORY DOCUMENTS

A paper prepared for the CNA Seminar: "What's New in Nuclear Standards",  
28 April 1981, Toronto, Ontario.

---

ABSTRACT

This document describes the Atomic Energy Control Board's (AECB) approach to the development and preparation of regulatory documents. The principal factors that have shaped the AECB's regulatory approach are identified as background to the evolution of regulatory documents as are a number of current influences that affect the present and future development of these documents. Also described are the process by which regulatory documents are prepared and published and the points of contact between this process and the Canadian Standards Association program for nuclear standards.

RÉSUMÉ

Ce document décrit la ligne de conduite suivie par la Commission de contrôle de l'énergie atomique (CCEA) dans le développement et la préparation des textes de réglementation. Les facteurs principaux qui ont déterminé le style réglementaire de la CCEA sont désignés dans les textes de réglementation qui se sont développés ainsi qu'un certain nombre d'influences courantes qui ont un effet sur le développement présent et futur de ces documents. Un exposé détaillé est aussi donné sur le processus par lequel les textes de réglementation sont préparés et publiés et les liens entre ce processus et le programme concernant les normes nucléaires de l'Association canadienne de normalisation.

## THE AECB'S REGULATORY APPROACH

The AECB's present approach to regulating nuclear activities and the manner in which this approach has developed are well documented elsewhere <sup>1</sup> and will not be dealt with here in any depth. It is, however, worth reiterating some of the principal factors that have shaped the AECB's regulatory style in order to set the background against which AECB regulatory documentation has evolved and further development continues.

The basic regulatory device chosen by the AECB is the requirement that persons or organizations wishing to undertake nuclear activities or to possess prescribed substances must, before doing so, be licensed by the AECB. One of the fundamental philosophical underpinnings of the AECB's approach to licensing is that the responsibility for maintaining health and safety resides with the licensee. In order to obtain a licence, an applicant must be able to assure the AECB that the activity in question can be undertaken such that any impact on health and safety will not only be acceptable but will also be as low as reasonably achievable. Thus, in practice, the AECB does not become involved in specifying in detail how any nuclear activity should be undertaken. Instead, an applicant is required to provide detailed information concerning the proposed activity. Effort by the regulatory staff is then concentrated on evaluating this proposal and, later, the licensed activity's actual performance. The framework for this evaluation is set by the fundamental principles and basic criteria that the AECB has developed.

From the regulatory point of view, this approach results in a minimal absolute need for the AECB to establish preemptive technical requirements that would dictate in detail the design of any nuclear facility or other activity involving prescribed substances. Where there is more of a need, however, is for what can be considered as statements of principle that give direction or guidance concerning the manner in which the AECB seeks to be assured that a proposed activity will be acceptably healthy and safe. This situation does not mean that neither detailed technical requirements nor specific health and safety criteria exist. For any particular activity these requirements and criteria are contained both in individual licence conditions and in the formal documentation submitted as part of a licence application which becomes by reference an integral part of the licence once it is granted.

It might be expected that, as experience is gained in regulating particular nuclear activities and as regulatory precedents in that area become set, it would become possible to establish and document an increasing number of both "technical requirements" and "statements of principle". This has happened to a degree and perhaps can be seen most clearly in the area of nuclear power reactor licensing where, resulting in part from further AECB staff development of the work of the Inter-Organizational Working Group <sup>2</sup>, four proposed regulatory documents, each addressing a specific aspect of safety assessment, have been produced and released for comment. <sup>3</sup> While final issue of these documents will mark a significant increase in the detail with which the AECB's regulatory requirements are formally documented, the additional detail is almost entirely contained in "statements of principle" rather than in any requirements that further delineate reactor design. It is also interesting to note that the AECB's overall approach to reactor safety, as described in recent AECB reports, shows quite clearly its heritage in the basic criteria and practices that were first formulated in the early 1960s. <sup>4</sup>

For nuclear facilities other than power reactors and for other activities the AECB applies the same fundamental philosophy. There are differences in the manner in which this philosophy is applied and these differences arise both from the diverse nature of the various activities regulated and the differing history of AECB regulatory involvement. A good example of this occurs with uranium mines where active and direct AECB involvement in health and safety regulation has been relatively recent (since the mid 1970s). In that situation the AECB became directly involved in actively regulating an old industry with well established practices where, from a regulatory point of view, it did not always appear possible to separate clearly the radiological health and safety matters from the non-radiological other than on a case-by-case basis. This stands in direct contrast to the situation with power reactors where the AECB was able to develop its regulatory approach in parallel with the development of the industry. Uranium mines also provide an example of another factor that differs between various nuclear activities and that is the concurrent but disparate degrees of involvement by other regulatory jurisdictions at both the federal and provincial levels of government. Factors such as these have resulted in the development of requirements and criteria that in each area of AECB regulation are a varying blend that results from the AECB's approach, the requirements of other regulatory bodies involved with which the AECB establishes a joint regulatory process, and practices that have developed within the particular industry in question.

A final factor that will be identified as having had some influence on the AECB's approach is the work of international bodies such as the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA). In many instances the influence has been indirect and has resulted simply through Canadian participation in the work of these bodies. In other cases it has been more direct, such as the effect of ICRP recommendations on the AECB's dose limits <sup>5</sup> and the adoption of the IAEA "regulation" <sup>6</sup> as the basis for regulating the transport and packaging of radioactive material.

#### PRESENT ENVIRONMENT AND FUTURE DIRECTIONS

There are a number of current influences that affect the AECB's development of regulatory documents.

The pressure for greater governmental openness and accountability is one to which all government organizations are subject. Notwithstanding, or perhaps even because of, the technical complexity of nuclear regulation, the AECB cannot operate on the assumption of latent and uncritical public trust. The skeptical view of the AECB sometimes taken by the media and interested sectors of the public stems in part from the lack of regulatory openness that these groups perceive to exist. It does not matter that what one commentator has characterized as the AECB's "professionally open" style of regulation is not deliberately publicly closed. <sup>7</sup> In moving towards more publicly open regulation it is necessary not only to remove both real and apparent barriers but also to facilitate actively public access to the regulatory process, where feasible. Regulatory documents, in setting out the criteria on which the AECB's licensing and compliance decisions are based, can play an essential role in providing part of

the needed access. This situation thus exerts a demand, not only for more regulatory documentation, but for documents that either on their own or with supporting material are understandable by the interested public.

Another influence arises from the relative youth of Canada's nuclear industry and the consequently rapid growth and diversification of both this industry and the AECB. As noted in the previous section, enough regulatory experience now exists to have established sufficient precedent and an adequate information base that regulatory document production is now possible. In the absence of such documentation, the increase in the number of personnel involved with regulatory matters, within both the industry and the AECB, creates the potential for inconsistency and misunderstanding in the application of what would otherwise remain tacitly understood criteria.

It must be remembered, however, that as long as the AECB's basic philosophy can be rather crudely summarised as "first tell us how you intend to do it and then we'll tell you whether its OK", there will exist very definite limits on the nature and the number of regulatory documents that will be produced. The above noted factors thus result as much in pressure on the AECB to adapt this philosophy as they do for more, and more detailed, documentation. Some would argue that, in practice, the AECB's philosophy has already moved significantly towards a more deterministic approach. Whether or not this is presently the case is debatable but it is reasonable to foresee some tendency to move in that direction as both the AECB and the nuclear industry continue to develop. It is equally reasonable to predict that any such movement will not be precipitate.

A third factor, that will also work to prevent any unwarranted proliferation of regulatory documentation, is the attention being paid within the federal government to regulatory reform. A special committee of the House of Commons was established on 23 May 1980 to examine this question and after an extensive series of hearings in a relatively short period of time issued its report and recommendations in December of the same year.<sup>8</sup> That report represents an eminently sensible and practical view of regulatory reform in the Canadian setting and many of the recommendations made by the committee are directly applicable to the AECB. What is most encouraging, however, is the extent to which measures either already adopted or under development by the AECB are consistent with those recommendations. These include such steps as advance notice and prior consultation in the development of regulatory initiatives, the establishment of a public list of persons interested in regulatory document development and the conduct of appropriate impact assessments. All of these measures should assist in ensuring that regulatory documents and the requirements they establish are necessary, effective and reasonable.

This rather cursory sketch of factors that influence the development of AECB regulatory documents leads to the hardly remarkable conclusion that the AECB must contend with pressures that are often in conflict and must ensure that an appropriate balance between them is achieved. The AECB has perhaps been slow in documenting those principles, criteria and requirements that it has developed and that are presently applied. The activity in regulatory document development that is now occurring is largely a response intended to correct

this deficiency. It should neither be seen as, nor result in, a marked change in the AECB's regulatory approach. In this connection the developments in a regulatory agency south of the border are worth mentioning. In a recent publication, the US Environmental Protection Agency (EPA) describes a reform in which, rather than requiring absolute compliance with the rules that have been developed as has been the case in the past, "if a company can find a better, more efficient, less costly way of getting the regulatory job done ... EPA will let the company do the job its way".<sup>9</sup> This "new, smarter approach to regulation" bears marked similarity in principle to the way the AECB has been doing its job all along.

#### THE REGULATORY DOCUMENT DEVELOPMENT PROCESS

The AECB has recently formalized the process by which regulatory documents are produced. This process is described in the internal guide attached as Appendix A. A regulatory document, in its narrowest sense, is a "tool" used by AECB staff in ensuring that the regulatory objectives of the AECB are met. This is not to say that regulatory documents do not serve other purposes, such as informing the public of the criteria and standards the AECB applies. The essential purpose of a regulatory document, however, is to establish requirements that those regulated must meet, to communicate these requirements to those affected and to give guidance on how the requirements may be interpreted and satisfied.

For the purposes of the development process, four categories of regulatory document are identified: regulations, generic licence conditions, regulatory policy statements and regulatory guides. The division is based on a decreasing degree of rigidity of application and is described in more detail in Appendix A.

The development process takes place in four steps. The first step concerns the internal development of a proposed regulatory document and may involve review by one or more of the AECB advisory committees.<sup>10</sup> The second step is aimed at obtaining input from sources external to the AECB. This involves releasing the proposed document for public comment as what is termed a "Consultative Document". This may be preceded by prior consultation with directly affected groups, such as industry, labour unions, and other government organizations. The final two steps - formalization and publication - are self-explanatory. In the case of regulations, Governor in Council approval must be obtained and the procedural requirements established by the Privy Council Office and the Treasury Board must be followed. The most significant of these is the requirement for a socio-economic impact analysis (SEIA) if the impact is judged to be in excess of defined criteria.<sup>11</sup>

The actual regulatory document development activity presently underway can be seen from the list attached as Appendix B. It should be evident that the documents produced and under development have been identified according to the needs of the various operational divisions of the AECB and not on the basis of any "master plan". This is quite consistent both with the view of these documents as individual "tools" and with the disparate nature of the AECB's various fields of regulation.

AECB REGULATORY DOCUMENTS AND CSA NUCLEAR STANDARDS

As specific activities in nuclear standards development will be covered by other speakers at this seminar, this concluding section will only attempt to identify the points of contact between that program and the AECB. Two main links exist.

The first occurs as a result of AECB staff participation in the Canadian Standards Association (CSA) nuclear standards program, both on the overall steering committee and, more particularly, in the individual technical committees that produce the standards. In this latter area, AECB staff participate in the development of about half of the presently identified nuclear standards. The AECB participation that does occur as well as contributing substantively, helps to ensure that the standard produced is acceptable from a regulatory standpoint. This can assist in making the regulatory process more efficient as standards development is essentially a consensus process in which the industry being regulated is involved. The use of "consensus standards" was a feature that was explicitly recognized and endorsed by the earlier mentioned parliamentary special committee. 12

The second link results from a direct reference to a CSA standard in an AECB regulatory document. This is only now beginning to occur. Given the earlier described regulatory approach of the AECB coupled with the early stages of development of both the nuclear standards and the AECB regulatory documents programs it would be expected that any such reference would normally be of a non-mandatory nature. The AECB can be expected to accept a standard as stipulating an acceptable way of doing things but may impose additional requirements of its own in any particular application. It can be expected that increasing use of this linkage will be made as both programs develop.

## FOOTNOTES

- 1) For a detailed account see the forthcoming publication "A History of the Atomic Energy Control Board" by Gordon H.E. Sims (INFO-0026, publication expected in late 1981). Specific descriptions can be found in the AECB staff presentations to the Ontario Select Committee on Ontario Hydro Affairs, available as AECB reports: AECB-1180-1 to -13.
- 2) The Inter-Organizational Working Group was established by the AECB president in 1977 with the purpose of clarifying and writing down the safety requirements for reactor safety. The group consisted of staff from both the utilities and the AECB under the chairmanship of a nuclear engineering professor. The group actually went beyond this initial purpose and proposed a number of major changes. See AECB-1149 (November 1978) for the report of this group.
- 3) These four proposed guides cover requirements for CANDU Nuclear Power Plants in the areas of:
  - Safety Analysis;
  - Containment Systems;
  - Shutdown Systems; and
  - Emergency Core Cooling Systems.

They are available as Consultative Documents C-6 to C-9 inclusive.

- 4) Z. Domaratzki, "Reactor Safety Requirements in Times of Change" (INFO-0005, June 17, 1980) is the most recent statement and provides an excellent summary of the matters addressed in the documents referred to in footnote 3.
- 5) Permissible doses are specified in the Atomic Energy Control Regulations, CRC, Vol. III, c. 365, (as amended by SOR/78-58 and SOR/79-422). The most recent recommendations of the ICRP affecting permissible doses are contained in ICRP Publication 26 (Pergamon Press, 1977). Following these recommendations, the AECB is presently considering revisions to s.19 and Schedule II of the Regulations.
- 6) "Regulations for the Safe Transport of Radioactive Materials", 1973 Revised Edition (As Amended), IAEA Vienna (1979). The AECB is presently in the process of preparing detailed regulations of its own that are based on the IAEA document and that interface with regulations being produced by the federal Department of Transport as the result of the recently passed Transportation of Dangerous Goods Act.
- 7) G.B. Doern, "Science and Technology in the Nuclear Regulatory Process: The Case of Canadian Uranium Miners", Canadian Public Administration, v. 21 no.1 (Spring 1978) pp 55-57. The author uses the terms "professionally open" and "democratically open" to establish two polar regulatory models. The AECB is seen, in its past and present style, as being close to the former model, which is characterized by "a high degree of mutual trust" and "frank criticism among professionally technical people". It is suggested that regulatory reform will cause the AECB to move towards the latter model, an evolution that "should not be seen as being achievable without costs".

- 8) House of Commons Canada, "Report of the Special Committee on Regulatory Reform" (December 1980).
- 9) U.S. Environmental Protection Agency, "Smarter Regulation", (January 1981).
- 10) Three advisory committees presently exist. The two most likely to be involved are the Advisory Committee on Radiological Protection and the Advisory Committee on Nuclear Safety. The third advisory committee is concerned with security.
- 11) Treasury Board Canada, Administrative Policy Manual, c.490, "Socio-Economic Impact Analysis" (December 1979). The criteria are give in Appendix B, p.23.
- 12) Report of the Special Committee on Regulatory Reform, pp. 35-36, (foot-note 8 above).

APPENDIX A

## GUIDE FOR THE PRODUCTION OF REGULATORY DOCUMENTS

This guide is intended to identify the major elements of a system for the production and revision of AECB regulatory documents. The objective is to achieve a reasonable level of consistency without introducing undue constraint in the preparation of regulatory documents that must serve a wide variety of needs.

### TYPES OF DOCUMENT

The system identifies four types of regulatory document as they will appear in final form.

- a) Regulations - these are vehicles by which the AECB can establish prohibitions, rights, obligations and powers subject to the limits set out in the Atomic Energy Control Act. Regulations are statutory instruments and have the full force of law. Once made, they generally leave little room for discretion either by those regulated or by the AECB.
- b) Generic Licence Conditions - standard sets of conditions that are included in particular AECB licences of a common type, unless specific circumstances indicate otherwise.
- c) Regulatory Policy Statements - firm expressions that particular "requirements" not expressed as Regulations or Licence Conditions be complied with or that any requirements be met in a particular manner but where the AECB retains the discretion to allow deviations or to consider alternative means of attaining the same objectives where a satisfactory case is made; and
- d) Regulatory Guides - guidance or advice on any aspect of the AECB's regulatory process that is given in a manner less rigid than that intended by Policy Statements.

In addition to these four final-form designations, the following terminology is used during the development of a regulatory document before it reaches final form.

- e) Proposal - the initial stage of development before any input from sources outside the AECB is obtained.
- f) Consultative Document - The designation attached to a proposed regulatory document at the time it is released outside the AECB for comment.

## PRODUCTION PROCESS

Production takes place in four steps as shown in Figure 1.

### 1. Proposal

The first step concerns the internal development of a proposed or revised regulatory document within the AECB but possibly including advice from AECB advisory committees. Depending on the nature of the proposed document, the proposal can either be an outline containing the principles on which the proposed document would be based or it can be a draft of the final document envisaged.

### 2. Consultation

This second step is aimed at obtaining input from sources external to the AECB through the preparation of a Consultative Document. In most cases it is envisaged that the Consultative Document will clearly indicate to which (or to which combination) of the four final document categories the proposal is intended to be allocated. This matter in itself is one on which comments may be received. Where revised or new regulations are being proposed, pre-examination by the Department of Justice must occur before release for comment outside the AECB.

In certain cases, after the period for public comment, a Consultative Document may be issued for "trial use". This is done for a limited period of time to gain practical experience. Following the period of trial use, the revised document is re-issued for further public comment prior to release in final form.

### 3. Formalization

The object of this third step is to decide on the final form of the document in terms of the four types designated.

### 4. Publication

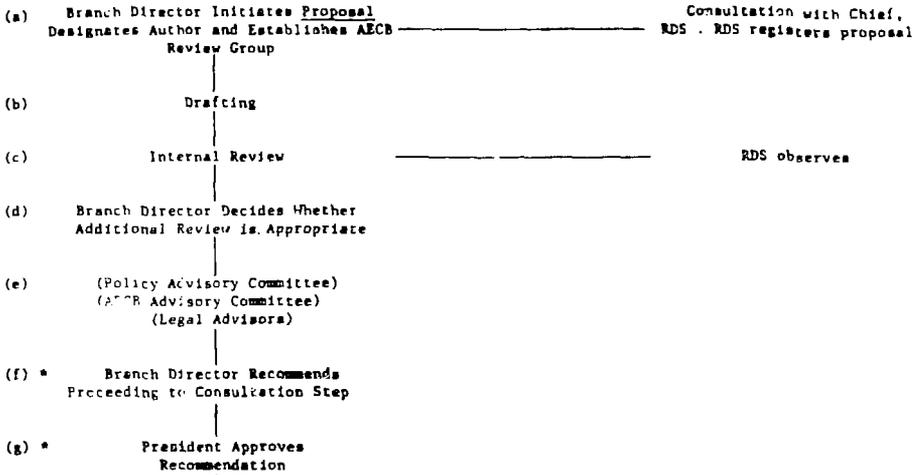
For Licence Conditions, Policy Statements and guides this is straightforward and is handled by the AECB. For Regulations, directives issued by the Treasury Board concerning socio-economic impact analysis (SEIA) and by the Privy Council Office concerning further approval steps must be complied with.

January 1981

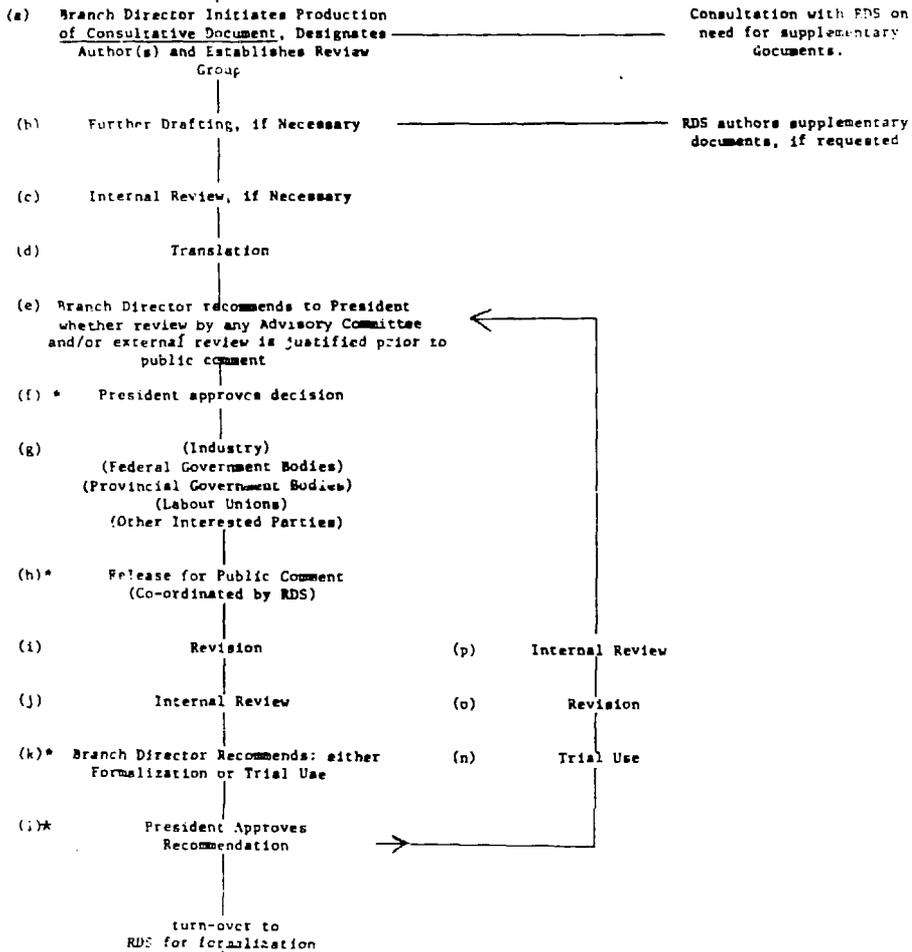
FIGURE 1

REGULATORY DOCUMENT  
PRODUCTION FLOW CHART

Proposal (Step 1)



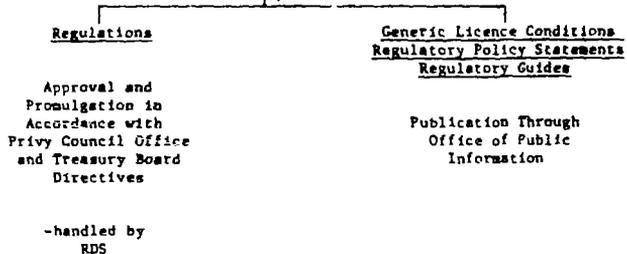
Consultation (Step 2)



Formalization (Step 3)

- (a) Formalization: Partitioning (if Necessary)  
Into: - Regulations  
- Generic Licence Conditions  
- Regulatory Policy Statements  
- Regulatory Guides
- (b) final legal advisor review
- (c)\* Branch Director Decides Whether Further Review is Appropriate
- (d) (Policy Advisory Committee)  
(AECB Advisory Committee)  
(Legal Advisors)
- (e)\* Branch Director Recommends Publication
- (f)\* President Approves  
(Board if appropriate)

Publication (Step 4)



RDS Regulations Development Section

\* Formal approval stage

January 1981.

APPENDIX B

ISSUED REGULATORY DOCUMENTS

REGULATORY POLICY STATEMENTS

R-10 The Use of Two Shutdown Systems in Reactors. 77-01-11

REGULATORY GUIDES

R-2 Guide to the Conduct of Public Meetings as Part of the Public Information Process for Uranium and Thorium Mine-Mill Facilities. 80-11-01

R-3 Guidelines for the Medical Surveillance of Atomic Radiation Workers at Uranium Mines, Mills and Refineries. 81-01-01

R-4 Guidelines for the Measurement of Airborne Radon Daughters in Mines. 81-01-01

CONSULTATIVE DOCUMENTS

C-1 Long Term Aspects of Uranium Tailings Management. 81-01-08

C-6 Requirements for the Safety Analysis of CANDU Nuclear Power Plants (35 p). 80-06

C-7 Requirements for Containment Systems for CANDU Nuclear Power Plants (21 p). 80-06

C-8 Requirements for Shutdown Systems for CANDU Nuclear Power Plants (16 p) 80-06

C-9 Requirements for Emergency Core Cooling Systems for CANDU Nuclear Power Plants (14 p). 80-06

## DOCUMENTS UNDER ACTIVE DEVELOPMENT

### REGULATIONS

Amendments to s.8 & 10 (Licensing Process), s.12 (Inspectors) and s. 27, 28 & 29 (Revocation, Suspension, Amendment).

Amendments to Part IV (Physical Security)

Amendments to s. 18 (Industrial Radiography)

Amendments to s. 19 (Permissible Losses)

Packaging of Radioactive Material for Transportation (New)

Uranium Mining (New)

### POLICY STATEMENTS AND GUIDES

Requirements for Safety Analysis

Performance Analysis for Containment Systems

Guide on Reliability Analysis

Policy Statement on Quality Assurance

Regulatory Guide on Quality Assurance

Requirements for Containment Systems

Requirements for Shut-Down Systems

Requirements for ECCS

Conduct of investigations of overexposure to radiation

Basic design requirements for radioisotope laboratories

A guide to the radioisotope process

A guide to the radioisotope licensing of teletherapy facilities.

A guide to the radioisotope licensing of brachytherapy facilities.

A guide to the radioisotope licensing of industrial gauges used in fixed installations.

Bioassay Requirements for Radioiodines.

Guide to radiography regulations.

Guide to the bioassay of Uranium at Mine-Mill Facilities

Guide for Geological Disposal.

Long Term Aspects of U Tailings Management.

Concept Assessment of Deep Geologic Disposal.

Quarterly Report for U Refinery.

Fuel Facility Licensing Part I, Regulatory Requirement.

Licensing of U Refineries.

Conduct of Public Meeting for a UF<sub>6</sub> Plant.

Medical Surveillance of ARWs in Fuel Fabrication Plants.

Monthly Report for D<sub>2</sub>O Plant.

Annual Report for D<sub>2</sub>O Plant.

Significant Event Report for D<sub>2</sub>O Plant.

Change Orders for D<sub>2</sub>O Plant.

