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# NRC LICENSING REQUIREMENTS DOD OPTIONS

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## DISCLAIMER

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# PREFACE

This report describes the licensing process (both safety and environmental) that would apply if the Department of Defense (DOD) chooses to obtain licenses from the U. S. Nuclear Regulatory Commission (NRC) for using nuclear energy for power and luminous sources. The specific nuclear energy sources being considered include:

1. Small or medium-size nuclear power reactors.

2. Radioisotopic thermoelectric generators with Sr-90 or Pu-238.

3. Radioisotopic dynamic electric generators with Sr-90 or Pu-238.

4. Applications of radioisotopes for luminous sources (lights) with H-3, Kr-85, or Pm-147.

The steps of the licensing process are summarized in the following sections, with particular attention given to the schedule and level of effort necessary to support the process.

# 1.0 INTRODUCTION

The NRC is the principal agency responsible for the licensing of uses of nuclear energy. This includes the design, construction, siting, and operation of nuclear power reactors and design, manufacture, distribution, and use of most devices containing radioactive materials. The NRC prepares the environmental impact statement for uses of nuclear energy based on the National Environmental Policy Act of 1969 as implemented by Executive Order 11514, and the Council on Environmental Quality's Guidelines of November 29, 1978. Transportation of radioactive materials is regulated by the U. S. Department of Transportation (DOT), with the NRC providing enforcement of DOT regulations. Some regulation of radioactive materials has been assumed by certain states through the NRC's Agreement States Program.

There is a variety of state legislation and regulations that affect the licensing of uses of nuclear energy, as well as Federally delegated authority. Federally delegated authority includes such areas as water quality standards, water quality management plans, and coastal zone management plans. State legislations and regulations include special restrictions on the construction of nuclear power plants, water supply allocation, public utility commission regulation, state environmental policy acts, and energy facility siting acts. Usually, the NRC requires that state approval be obtained prior to the issuance of a license.

As authorized by the NRC, the Atomic Safety and Licensing Board (ASLB) can review license applications in a public hearing forum, inviting public participation. The hearings conducted by the ASLB are used to resolve any final matters concerning a license application. The hearing allows an opportunity for interested members of the public to participate directly in the licensing process.

This report is limited in scope and only estimates the costs to the Department of Defense in schedule and level of effort to support the licensing of the use of nuclear energy. The discussion on other options available to DOD (Section 5.0) briefly touches on some of the benefits of an NRC licensing review.

The DOD is exempt from the NRC licensing process, and therefore its participation in the process would be voluntary. The licensing process can be costly, as studies suggest that the licensing process accounts for one-third to one-half of the schedule duration to build a nuclear power plant (1.1, 1.2). Changing licensing requirements are suggested to be one of the major causes of schedule lengthening because of the resulting reengineering required to accommodate the changes (1.3).

## 2.0 STATUTORY AUTHORITY DISCUSSION

The Atomic Energy Act of 1954 assigned several primary responsibilities to the former Atomic Energy Commission (AEC). In summary, these responsibilities were to promote and develop peaceful uses of atomic energy and provide reasonable assurance that such uses did not result in undue risks to the health and safety of the general public. With respect to regulation, the act had a wide scope, including the licensing of: (1) uses of radioactive materials and sources in industry, research, and radiography, (2) reactor fuel fabrication and reprocessing, (3) subcritical assemblies, (4) packaging of radioactive materials for transport, (5) construction and operation of research, test, and power reactors, and (6) licensing of individual operators. In 1957, the Act was amended to require the AEC to hold public hearings on each application for a license for a production and utilization facility. In 1962, another amendment eliminated the mandatory hearing at the operating license stage and provided for the designation of an Atomic Safety and Licensing Board to conduct hearings on construction permit applications.

The Energy Reorganization Act of 1974 separated the promotional functions formerly carried out by the AEC from the licensing and related regulatory functions and assigned the latter to the newly created Nuclear Regulatory Commission. By this Act, the NRC is delegated authority for licensing and regulation involving all facilities and materials licensed under the Atomic Energy Act of 1954, as amended, including such matters as safeguards, transportation, special nuclear materials, and confirmatory research.

The National Environmental Policy Act of 1969 (NEPA) set forth a national policy which encourages harmony between man and his environment. In summary, this Act and Executive Order 11514 of March 5, 1970, which augmented it, required environmental impact statements on major Federal actions, review by Federal, state, and local agencies, and submittal of a final detailed statement to the President via the Council on Environmental Quality.

In July 1971, a significant court decision was issued by the U. S. Court of Appeals for the District of Columbia regarding the Calvert Cliffs nuclear power plant. The Court interpreted that NEPA requires the former AEC, as the agency with overall responsibility for the approval of nuclear facilities, to make an independent evaluation of environmental matters whether or not other Federal or state agencies have previously certified that their own environmental standards are satisifed. This assessment must consider benefits weighed against environmental costs and alternatives which affect the cost/benefit balance. As a consequence of the Calvert Cliffs decision, four new areas of consideration were included in the environmental statements for nuclear power plants: (1) transportation of nuclear fuel - new and irradiated, (2) transmission lines, (3) accidents, and (4) a cost-benefit analysis of the environmental costs of the plant versus its economic benefits.

The AEC adopted an Interim Policy Statement in January 1973 (38 FR 2679, January 29, 1973) regarding the effect of amendments to the Federal Water Pollution Control Act (FWPCA) upon the AEC's responsibilities in implementing NEPA and the FWPCA amendments of 1972. This Interim Policy Statement and the Memorandum of Understanding are still in effect under the NRC.

As noted above, as part of its statutory duties, the role of the NRC is to oversee the design, construction, and operation of commercial nuclear reactor facilities in order to determine that reasonable assurance is provided for the health and safety of the public and the protection of the environment, and to give appropriate consideration to antitrust matters.

Under Section 91 of the Atomic Energy Act of 1954, as amended, the Department of Defense is authorized to perform certain activities regarding nuclear energy and materials which are governed by the Act. Section 110 of the same Act excludes the activities of DOD authorized in Section 91 of the Atomic Energy Act, as amended, from the licensing provisions of this Act.

# 3.0 SMALL OR MEDIUM-SIZE NUCLEAR POWER REACTORS

## 3.1 Applicable Regulations

In exercising the statutory authority given to it by the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, the NRC has codified requirements that must be satisfied by applicants and licensees regarding the design, construction, and operation of nuclear power reactors and the storage, handling, and shipment of the fuel and radioactive sources associated with such reactors. These requirements are specified in the NRC's rules and regulations, Title 10 of the Code of Federal Regulations (CFR). The specific parts of Title 10 that would apply in the subject case are Parts 20, 21, 50, 51, 55, 70, 71, 72, 73, 100, and 170. The particular portions of the regulations applied during the NRC review of a reactor license application are identified in the NRC's Standard Review Plan (see below).

Subsection 10 CFR 50.11(a) exempts the Department of Defense from all licensing requirements regarding the activities that DOD is authorized to perform under Section 91 of the Atomic Energy Act of 1954, as amended. As a result of this exemption, any participation by DOD in the NRC's licensing process would be strictly on a voluntary basis.

If DOD were to elect to participate in the NRC's licensing process for the purpose of obtaining a license for a small or medium-size nuclear power reactor that would be used to provide power for a DOD facility, another matter would require early consideration. Under existing NRC regulations, the NRC may issue two classes of licenses, Class 104 and Class 103 (10 CFR 50.20 - 50.22).

Class 104 licenses deal primarily with medical therapy and research and development facilities. However, under 50.21(b)(3), a Class 104 license can be issued to an applicant for "a production or utilization facility for industrial or commercial purposes when specifically authorized by law."

Class 103 licenses cover commercial and industrial facilities. However, whether the use that DOD would make of a reactor would meet the 50.22 definition of a commercial or industrial facility would have to be determined. Of the two types, Class 103 might be more applicable, but this is not obvious. Therefore, either special authorizing legislation from the Congress may be necessary, or the NRC's regulations may have to be changed to include the specific case of a license for DOD.

As noted in Regulatory Guide 1.49, "Power Levels of Nuclear Power Plants," the NRC specified, until further notice, a power level of 3800 MWt as an upper limit restriction on the size of nuclear power reactors that it will license. To date, the NRC has not removed this restriction. However, currently no lower limit restriction on reactor size exists. A small or medium size reactor would be exempted from certain of the NRC's regulations, depending on its size. Specifically, for reactors with an authorized power level that is less than 250 MWt, the size of the Emergency Planning Zone (EPZ) required by 10 CFR 50.33(g) may be determined on a case-by-case basis, instead of the 10-mile radius plume exposure pathway EPZ and 50-mile radius ingestion pathway EPZ specified therein. In addition, the information requirements for the antitrust review are reduced, at the NRC's discretion, for reactors with electrical generating capacity between 200 MWe and 1400 MWe, and eliminated completely if the electrical generating

capacity of the reactor is less than or equal to 200 MWe. However, because DOD is a government department, the antitrust requirements might not apply to DOD.

## 3.2 Regulatory Guides

As stated above, the NRC's licensing requirements are published in particular parts of Title 10 of the Code of Federal Regulations. In many areas, these requirements are quite general. Hence, in some instances, the NRC staff has taken positions in individual licensing cases that have established methods that the staff considers acceptable for implementing the requirements of the regulations. The documents containing these positions are called Regulatory Guides.

The primary purposes of Regulatory Guides (3.1) are (1) to describe and make publicly available methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, and (2) to provide guidance to applicants regarding certain information needed by the NRC staff in its review of license applications.

Regulatory Guides are not intended as substitutes for regulations, and, therefore, compliance with these guides is not required. Methods and solutions different from those specifed in the guides will be found acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the NRC.

The Regulatory Guide series is an expansion of the series entitled "Safety Guides for Water-Cooled Nuclear Power Plants." The Regulatory Guides deal with all types of production and utilization facilities, environmental and siting matters, protection and accountability of special nuclear materials, radiation protection, products containing radioactive materials, fabrication and reprocessing of nuclear fuels, and antitrust matters. The Regulatory Guide series is organized as follows:

Division

1 - Power Reactor Guides

2 - Research and Test Reactor Guides

3 - Fuels and Materials Facilities Guides

4 - Environmental and Siting Guides

5 - Materials and Plant Protection Guides

6 - Product Guides

7 - Transportation Guides

8 - Occupational Health Guides

9 - Antitrust Review Guides

10 - General Guides

The particular guides that are employed in the NRC review of a reactor licensing application are identified in the Standard Review Plan (see Section 3.4).

## 3.3 Standard Format and Content (Information Submittal Requirements)

Section 50.34 of 10 CFR Part 50 requires that each application for a construction permit for a nuclear reactor facility include a Preliminary Safety Analysis Report (PSAR), and that each application for a license to operate such a facility include a Final Safety Analysis Report (FSAR). Section 50.34 specifies in general terms the information to be supplied in these Safety Analysis Reports (SARs).

The principal purpose of the SAR is to inform the NRC of the nature of the plant, the plans for its use, and the safety evaluations that have been performed to evaluate whether the plant can be constructed and operated without undue risk to the public. The SAR is the principal document for the applicant to provide the information needed to understand the basis on which this conclusion has been reached; it is the principal document referenced in the Construction Permit or Operating License that describes the basis on which the permit or license is issued; and it is the basic document used by NRC inspectors to determine whether the facility is being constructed and operated within the licensed conditions. Therefore, the information contained in the SAR should be timely, accurate, complete, and organized in a format that provides easy access.

The purpose of the "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants," Regulatory Guide 1.70 (Reference 3.2), is to indicate the information to be provided in the SAR and to establish a uniform format for presenting the information. Use of this format will help ensure the completeness of the information provided, will assist the NRC staff and others in locating the information, and will aid in shortening the time needed for the review process.

The Standard Format represents a format for SARs that is acceptable to the NRC staff. Since it is a Regulatory Guide, conformance with the Standard Format is not required. Safety Analysis Reports with different formats will be acceptable to the staff if they provide an adequate basis for the findings requisite to the issuance of a license or permit. However, because it may be more difficult to locate needed information, the staff review time for such reports may be longer, and there is a greater likelihood that the staff may regard the report as incomplete.

There are three editions of the Standard Format: one for light-water-cooled nuclear power reactors (LWR Edition), one for high-temperature gas-cooled reactors (HTGR Edition), and one for liquid metal fast breeder reactors (LMFBR Editon).

## 3.4 Standard Review Plan

The Standard Review Plan (SRP), published in its latest revision in 1981 by the NRC as NUREG-0800 (Reference 3.3), is prepared for the guidance of NRC staff reviewers in the Office of Nuclear Reactor Regulation in performing safety reviews of applications to construct or operate nuclear power plants.

The principal purpose of the SRP is to assure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate proposed changes in the scope and requirements of reviews. It is also a purpose of the SRP to make information about regulatory matters widely available and to improve communication and understanding of the staff review process by interested members of the public and the nuclear power industry.

The NRC's safety review is primarily based on the information provided by an applicant in a Safety Analysis Report (SAR).

Section 50.34 (of 10 CFR Part 50) specifies, in general terms, the information to be supplied in a SAR. As stated above, the specific information required by the NRC staff for an evaluation of an application is identified in Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition." The SRP sections are keyed to the Standard Format, and SRP sections are numbered according to the section numbers in the Standard Format. Review plans have not been prepared for SAR sections that consist of background or design data which are included for information or for use in the review of other SAR sections.

The Standard Review Plan is written so as to cover a variety of site conditions and plant designs. Each section is written to provide the complete procedure and all acceptance criteria for the areas of review pertinent to that section. However, for any given application, the NRC staff reviewers may select and emphasize particular aspects of each SRP section as is appropriate for the application. In some cases, the major portion of the review of a plant feature may be done on a

generic basis with the designer of that feature rather than in the context of reviews of particular applications from utilities. In other cases, a plant feature may be sufficiently similar to that of a previous plant so that a de novo review of the feature is not needed. For these and other similar reasons, the NRC staff may not carry out in detail all of the review steps listed in each SRP section in the review of every application.

The individual SRP sections address, in detail, who performs the review, the matters that are reviewed, the basis for review, how the review is accomplished, and the conclusions that are sought. The safety review is performed by 25 primary branches. One of the objectives of the SRP is to assign the review responsibilities to the various branches and to define the sometimes complex interfaces between them. Each SRP section identifies the branch that has the primary review responsibility for that section. In some review areas the primary branch may require support, and the branches that are assigned these secondary review responsibilities are also identified for each SRP section.

Each SRP is organized into five subsections as follows:

(I) Areas of review

(II) Acceptance criteria

(III) Review procedures

(IV) Evaluation findings

(V) References (including NRC regulations and Regulatory Guides)

Although the SRP is directed toward light-water-cooled nuclear power reactors, the NRC staff will adopt the SRP for use in reviews of other reactor types, where applicable.

## 3.5 Reactor Licensing Process

### 3.5.1 Scope

This section describes the current NRC licensing process (3.4) for nuclear power reactors in its entirety. The process described herein would be applicable if DOD elected to pursue issuance of an operating license from the NRC for a small or medium-size nuclear power reactor to provide power for a DOD facility. Ways in which DOD could shorten the time required for this process are discussed in Section 3.5. Other options available to DOD that do not involve the granting of an operating license by the NRC are discussed in Section 6.0.

The current reactor licensing process is a two-stage process involving the issuance of a construction permit and an operating license.

### 3.5.2 Construction Permit Stage

Before a utility-applicant or other company can build a nuclear power plant at a particular site, the applicant must obtain a construction permit from the NRC. As a major part of the application for a construction permit, an applicant must file a Preliminary Safety Analysis Report (PSAR). This document presents the design criteria and preliminary design information for the proposed reactor and comprehensive data on the proposed site. The report discusses various hypothetical accident situations and the safety features which will be

provided to prevent accidents or, should they occur, to mitigate their effects on both the public and the facility's employees. The applicant must also submit a comprehensive Environmental Report (ER) providing a basis for the evaluation of the environmental impact of the proposed plant. Further, information must be submitted by the applicant for use by the Attorney General and the NRC staff in their reviews of the antitrust aspects of the proposed plant.

An applicant for a construction permit for a nuclear power plant may tender the required information in three parts. One part is accompanied by the Environmental Report and site suitability information, and the second part by the PSAR. Tendering of the first part may precede the tendering of the other by no longer than six months. Whichever of the above parts is tendered first must also include the fee and other general and financial information. The third part, consisting of antitrust information, is tendered nine to thirty-six months before the other information in order for the Attorney General and the NRC staff to begin the antitrust review.

At some time during the period when the applicant is preparing its application for a construction permit, usually about six to twelve months prior to tendering, the NRC staff holds a general introductory meeting in the area of the proposed site in order to familiarize the public with the safety and environmental aspects of the proposed application, including type of plant, the regulatory process, and the provisions for public participation in the licensing process. Additional public meetings of this kind (that is, those which are conducted specifically for the convenience of public observation and participation) are held during the course of the reactor licensing process.

When an application is submitted, the NRC staff performs an acceptance review to determine whether it contains sufficient information to satisfy the NRC requirements for a detailed review. If the application is not sufficiently complete, the staff makes specific requests for additional information. The application is formally accepted by NRC only if it meets certain minimum acceptance criteria. When the PSAR is submitted, the NRC also conducts a detailed review and an inspection of the applicant's quality assurance program, covering design and procurement.

As soon as an application for a construction permit is received by the NRC, copies are placed in the NRC Public Document Room. As soon as the ER or PSAR or early site information is received, copies are also placed in the local Public Document Room near the proposed site. Copies of all future correspondence and documents relating to the application are placed in these locations, and are available to every member of the public. Also, a press release announcing receipt of the application is issued by the NRC. Upon docketing (acceptance) of the applicant's application for a construction permit, copies are sent to Federal, state, and local officials and a notice of its receipt is published in the Federal Register.

3.5.2.1 Safety Review

The application is reviewed to determine that the plant design is consistent with NRC requirements. Design methods and of calculation procedures are examined to establish their validity. The NRC staff makes checks of actual calculations and other analysis and design procedures to establish the validity of the applicant's design and to determine that the

applicant has conducted its analysis and evaluation in sufficient depth and breadth to support required findings with respect to safety.

During the NRC staff's review, the applicant is required to provide such additional information as is needed to complete the evaluation. The principal features of the staff's review can be summarized as follows:

1. A review is made of the population density and use characteristics of the site environs, and the physical characteristics of the site, including seismology, meteorology, geology, and hydrology, to determine that these characteristics have been evaluated adequately and have been given appropriate consideration in the plant design, and that the site characteristics are in accordance with the siting criteria (10 CFR Part 100), taking into consideration the design of the facility, including the engineered safety features provided.

2. A review is performed of the preliminary facility design, and of proposed programs for fabrication, construction and testing of the plant structures, systems, and components important to safety to determine if the are in accord with NRC requirements, and that any departures from these requirements have been identified and justified.

3. Evaluations are made of the anticipated response of the reactor to various postulated operating transients and to a broad spectrum of hypothetical accidents. The potential consequences of these

hypothetical accidents are then evaluated conservatively to determine that the calculated potential offsite doses that might result, in the very unlikely event of their occurrence, would not exceed the NRC guidelines for site acceptability.

4. A review is made of the applicant's proposed plans for the conduct of plant operations, including the organizational structure, the technical qualifications of operating and technical support personnel, the measures taken for industrial security, and the planning for emergency actions to be taken in the unlikely event of an accident that might affect the general public. An important aspect of this review includes an assessment of the applicant's proposed programs for quality assurance and quality control to assure compliance with NRC requirements. These reviews form the basis for determining whether the applicant is technically qualified to operate the plant and whether effective organizations and plans for safe operation of the plant have been established.

5. Evaluations are made of the design of the proposed systems provided for control of the radiological effluents from the plant to determine that these systems can control the release of radioactive wastes from the plant within the limits specified by NRC requirements, and that the applicant will operate the plant in such a manner as to reduce radioactive releases to levels that are as low as is reasonably achievable.

The safety review is conducted by members of the NRC staff and its consultants over a period of about one to two years. The staff and applicant interact frequently during the course of the review in working-type meetings. At these meetings information is exchanged, problems are discussed and resolved, and staff positions are clarified. Intervenors and other interested members of the public are generally invited to staff-applicant meetings as observers.

The review process includes the consideration of programs proposed by an applicant for a construction permit to verify plant design features and to confirm design margins. The review process includes consideration of basic research and development programs necessary to assure the resolution of safety questions associated with safety features or components. The applicant must identify any research and development work that will be conducted to confirm the adequacy of, or to resolve any safety questions associated with, the design of a particular facility, along with a schedule for completion of that research and development work. All such safety questions must be resolved prior to operation of the facility. After completion of construction, nuclear power plants are subject to operating license procedures and requirements. Data obtained from research and development programs on particular facilities and from the NRC's safety research program are factored into these licensing reviews.

When the review and evaluation of the application progresses to the point where the staff concludes that acceptable criteria, preliminary design information, and financial information are documented adequately in the application, a Safety Evaluation Report is prepared. This report presents a summary of the review and evaluation of the application by the NRC staff relative to the anticipated effect of the proposed facility on the public health and safety.

### 3.5.2.2 ACRS Review

The Advisory Committee on Reactor Safeguards (ACRS), an independent statutory committee established to provide advice to the NRC on reactor safety, reviews each application for a construction permit for a nuclear power plant. The ACRS is composed of a maximum of fifteen members who, though not NRC employees, are appointed by the NRC for terms of four years each. The members are experienced, technically trained individuals selected from various technical disciplines, having applicable experience in industry, research activities, and in the academic area. The ACRS also makes use of consultants in specialized technical disciplines.

As soon as an application for a construction permit is docketed, copies of the PSAR are provided to the ACRS. Each application is assigned to an ACRS subcommittee, usually made up of four to five ACRS members. During the course of the review by the staff, the ACRS is kept informed of the staff's information from the applicant and of meetings held, so that the subcommittee is aware of any developments that may warrant a change in the plant. In those cases where the plant is a "standard design" and the site appears generally acceptable, the subcommittee review does not begin until the staff has nearly completed its detailed review of all the safety-related features of the plant. Where new or modified concepts or special site considerations are involved, the ACRS subcommittee begins its formal review earlier in the process, selecting appropriate stages in the staff review to begin a series of meetings with the applicant and the staff.

Normally, before the full Committee considers a project, the NRC staff provides its Safety Evaluation Report (SER) for the Committee's information. This staff report and the report of

the ACRS subcommittee form the basis for Committee consideration of a project. Special attention is given to those items which are of particular safety significance for the reactor involved and any new or advanced features proposed by the applicant. The full Committee meets at least once with the NRC staff and with the applicant to discuss the application. These meetings are open to the public. When the Committee has completed its review, its report is submitted to the NRC in the form of a letter to the Chairman, which is made public.

The NRC staff prepares one or more supplements to the Safety Evaluation Report to address the safety issues raised by the ACRS in its report and to include any other information made available since issuance of the original Safety Evaluation Report.

3.5.2.3 Environmental Review

Either concurrent with or separate from the radiological safety review, an environmental review is performed by the NRC staff and its consultants to evaluate the potential environmental impact of the proposed plant, as well as to provide comparisons between the benefits to be derived and the possible risk to the environment. The staff's environmental review is based on the applicant's Environmental Report (ER). The content and scope of the ER are specified in Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Stations." Preparation of this document represents a substantial effort on the part of the applicant. After completion of this review, a Draft Environmental Statement (DES), containing conclusions on environmental matters, is issued by the NRC staff. The DES is circulated for review and comments

by the appropriate Federal, state, and local agencies, as well as by private individuals and organizations. After receipt of all comments and resolution of any outstanding issues, a Final Environmental Statement (FES) is issued. The SER and its supplements and the FES constitute the NRC staff's primary evidence at the subsequent public hearings.

3.5.2.4 Public Hearing

The law requires that a public hearing be held before a construction permit may be issued for a nuclear power plant. Soon after an application is docketed, the NRC issues a notice of the hearing which will be held after completion of the NRC staff's safety and environmental reviews. In addition, the hearing is noticed in several newspapers in the vicinity of the proposed plant, and a public announcement is issued by the NRC. Opportunity is afforded for members of the public to participate in the hearing. Members of the public may submit written statements to the licensing board to be entered into the hearing record, they may appear to give direct statements at the hearing, or they may petition for leave to intervene as full parties in the hearing. At an early stage in the review process, potential intervenors are invited to meet informally and discuss with the NRC staff their concerns with respect to the proposed facility.

The public hearing is conducted by a three-member Atomic Safety and Licensing Board appointed from the NRC's Atomic Safety and Licensing Board Panel. The board is composed of one lawyer, who acts as chairperson, and two technically qualified persons. The hearing may be a combined safety and environmental hearing or, in the case of a split application, separate hearings. The board considers all the evidence which

has been presented, together with findings of fact and conclusions of law filed by the parties, and issues an initial decision. If the initial decision regarding NEPA and safety matters is favorable, a construction permit is issued to the applicant by the Director of Nuclear Reactor Regulation. The board's initial decision is subject to review by an Atomic Safety and Licensing Appeal Board and by the Commission.

3.5.2.5 Limited Work Authorization

NRC regulations provide that the Director of Nuclear Reactor Regulation may authorize limited construction work to be carried out prior to the issuance of the construction permit. This authorization is known as a Limited Work Authorization (LWA). The regulations provide for the authorization of two types of work. One type may authorize site preparation work, installation of temporary construction support facilities, excavation, construction of service facilities, and certain other construction not subject to the quality assurance requirements. The second type of LWA may authorize the installation of structural foundations.

An LWA may be granted only after the licensing board has made all of the National Environmental Policy Act findings required by the Commission's regulations for the issuance of a construction permit, and has determined from a radiological health and safety standpoint that there is reasonable assurance that the proposed site is a suitable location for a nuclear power reactor of the general size and type proposed. The second type may be granted if, in addition to the findings described above, the hearing board determines that there are no unresolved safety issues relating to the work to be authorized.

#### 3.5.2.6 Antitrust Review

The law requires that antitrust aspects of a nuclear power plant license application must be considered in the licensing process. The antitrust information submitted by the applicant is sent to the Attorney General for advice on whether activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws. Upon receipt, the Attorney General's advice is promptly published, and opportunity is provided for members of the public to raise antitrust issues. An antitrust hearing may be held based on the recommendation of the Attorney General or on the petition of an interested party. In any event, the NRC must make a finding on antitrust matters. Antitrust hearings are held separately from hearings on environmental and safety matters.

### 3.5.3 Operating License Stage

When the construction of the nuclear plant has progressed to the point where final design information and plans for operation are ready, the applicant submits the Final Safety Analysis Report in support of the application for an operating license. The FSAR sets forth the pertinent details on the final design of the facility, including final containment design, design of the nuclear core, and waste handling system. The FSAR also provides proposed operational Technical Specifications and an emergency plan. The Environmental Report is also updated and submitted as part of the operating license application. Again the NRC staff makes a detailed review of the information. Amendments to the application and reports may be submitted from time to time. The NRC staff again prepares a Safety Evaluation Report (regarding the operating license) and Draft and Final Environmental Statements, and, as

during the construction permit stage, the ACRS makes an independent evaluation and presents its advice to the Commission.

A public hearing is not mandatory with respect to an operating license application. However, soon after acceptance for review of the operating license application, the NRC publishes notice that it is considering issuance of the license. The notice provides that any person whose interest might be affected by the proceeding may petition the NRC for a hearing. If a public hearing is held, the same decision process described for the construction permit hearing is applicable.

3.5.3.1 Safeguards

The NRC's reactor safeguards program is directed primarily toward the physical protection of nuclear power plants against acts of sabotage which could result in releases of radioactive materials in amounts sufficient to represent a hazard to the public health and safety. To minimize the risk from such acts, security plans have been a required part of the safety review of operating license applications since the early 1960's. In November 1973, the former AEC explicitly incorporated into its rules a requirement that physical security plans be submitted as part of the operating license application. Guidance, in the form of Regulatory Guide 1.17, was also issued in 1973. This guide endorsed an industry standard, ANSI N 18.17-1973, "Industrial Security for Nuclear Power Plants."

Aware of increased public concern for the potential consequences of acts of willful destruction, the NRC codified additional requirements for the physical protection of

licensed nuclear power plants. These requirements were published in 10 CFR 73.55 in February 1977. These regulations specify a postulated threat level to be assumed in the design and evaluation of physical security systems for nuclear power plants. 10 CFR 73.55 also specifies detailed requirements regarding a physical security organization, a response force, access controls, protection of vital equipment, intrusion detection systems, redundant alarm systems, lighting of protected areas, and redundant communications links with offsite law enforcement agencies.

#### 3.5.3.2 Decommissioning

The NRC's requirements regarding the determination of an applicant's financial qualifications for a facility operating license are specified in Section 50.33(f) and Appendix C to 10 CFR Part 50. Under these requirements, applicants must submit sufficient information regarding construction costs, related fuel cycle costs, operational costs, the estimated costs of permanently shutting the facility down and maintaining it in safe condition, and the availability of funds to cover these costs so that the NRC can conclude that the applicant is financially qualified to perform these activities.

### 3.5.4 Operations

Each license for operation of a nuclear reactor contains Technical Specifications, which set forth the particular safety and environmental protection measures to be imposed upon the plant, and the conditions of its operation that are to be met in order to assure protection of both the health and safety of the public and of the surrounding environment. Operational aspects of the plant also include the approved

safeguards measures and procedures and the approved emergency plan. Once licensed, a nuclear facility remains under NRC surveillance and undergoes periodic inspections throughout its operating life. In cases where the NRC finds that substantial additional protection is necessary for the public health and safety or the common defense and security, the NRC may require "backfitting" of a licensed plant. Backfitting consists of the addition, elimination, or modification of structures, systems, or components of the licensed plant.

### 3.5.5 Schedule and Level of Effort Required to Support NRC Licensing

As the preceding discussion indicates, the current two-stage NRC licensing process is quite complex. Much information has been published on the length of time required for the reactor licensing process. Figure 3-1 (3.5) shows the NRC's standard schedule for the construction permit review phase of the NRC's reactor licensing process for the case of a custom plant design. According to Figure 3-1, the entire phase, from the time an applicant notifies the NRC of its intent to file an application for a construction permit (assumed to occur one year before filing) to issuance of the construction permit, is estimated to take 30 months for a non-contested hearing and almost 32 months for a contested hearing case. Stated in terms of the time between docketing and construction permit issuance, these would be 18 and 20 months, respectively. Figure 3-2 (3.5) shows the corresponding NRC standard schedule for the operating license review portion of the licensing process for the case of a custom design. Figure 3-2 estimates about 24 months from tendering of the FSAR to operating license issuance (assumed to coincide with completion of plant

construction). This schedule estimate also assumed that no public hearing was required. If a hearing were required, additional time would be needed to complete the hearing process. The standard schedule for the hearing would be the same as that shown in Figure 3-1 for the construction permit review. Based on a comparison between the two figures, the operating license review process should still be completed before completion of construction, even with a contested hearing.

Unfortunately, experience has proven that the "standard" schedule estimates represent the exception, rather than the rule, with regard to the length of the reactor licensing process. For example, Table 2.5 of NUREG-0292 (3.6) summarized recent construction permit review experience for 21 light water power reactors covering fiscal years 1975-77. The results indicate that the length of time required from PSAR docketing to construction permit issuance for the plants surveyed ranged from 17.5 months to 56.5 months, with an average duration of 30.4 months. This set of data included several standardized designs. Table III-8 of NUREG-0427 (3.7) reported analogous data for a set of custom plants. The results in that case indicated a range from 18.1 months to 46.2 months duration, with an average duration of 32.1 months. Both sets of results compare unfavorably with the NRC standard estimated duration of 18 months for an uncontested hearing case and 21 months for a contested hearing case.

According to data published in NUREG-0030 (3.8) and NUREG-0580 (3.9), the increase in the length of time required for the operating license review phase of the licensing process was even more significant. For a set of 13 plants which either finished construction in 1981-82 or expect to complete

construction in early 1983, the average time required for the operating license review was approximately 70 months. Of course, the licensing review of each of the plants was impacted by the Three Mile Island accident; the extent of that impact could not be determined within the scope of this project. Since data regarding the length of operating license reviews were not readily available in a timely manner, an effort was made to determine whether the 70-month average duration represented a reasonable estimate of the length of the operating license review phase. This involved the construction duration data published in NUREG-0030 (3.8). This document reports the length of time that elapsed between the start of plant construction and the start of fuel loading. In terms of licensing parameters, this is approximately the time between construction permit issuance and issuance of the operating license. This period includes, of course, the operating license review. Data for plants completed before 1970 show an average construction duration of 46.0 months for a total of 12 plants. In 1970, the average duration for four plants was 47.6 months. By 1972, the average duration had increased to 60.9 months for six plants. Although the average duration remained fairly constant from 1973 through 1975 at about 75 months, it had increased to 90.0 months by 1977.

Data for 1980 and 1981 show that the average construction duration time has increased to approximately 130 months. Projected construction durations for plants still under construction indicate that, at best, the average construction duration may decrease slightly over the next two years, with a minimum average duration for that period of 109.3 months projected for 1983. After that time, the average duration is expected to increase steadily each year until all current construction has been completed. Delays in completion of

construction can be caused by a number of factors, one of which is certainly the licensing process with its climate of changing regulatory requirements. It is reasonable to assume that a corresponding increase in the average length of time required for the operating license review has occurred since 1970.

Tables 3-1 and 3-2 show the levels of effort required to support each portion of the construction permit and operating license review phases. These figures were based upon industry and NRC estimates of the manpower expenditure required to support the operating license review phase of the licensing process of between 25 to 30 man-years. It was assumed that a similar level of effort would be required to support the construction permit review phase. Data for the manpower expended in each portion of the operating license review phase are not readily available. Therefore, the manpower estimates shown in the tables were based on the fraction of total schedule time represented by each portion of the operating license review.

As was stated previously, these estimates should be considered a lower bound on the schedule and level of supporting effort required, if DOD were to apply for licenses from the NRC to construct and operate a small to medium-size nuclear power reactor. This is due to the fact that the estimates of the length of time for each portion of the licensing review were based on the NRC standard schedule, which is obviously too optimistic (3.5-3.15) due to the effects of the current socio-economic climate and changing regulatory requirements (e.g., post-TMI-2 requirements). Based on the information available, we conclude that, if DOD were to attempt to obtain licenses

for a custom-design reactor to be located on an arbitrary site, the resulting licensing review could have a considerably long duration, with resulting adverse economic effects.

Within the current regulatory framework, the NRC's Standardization Policy (3.7) appears to offer the most potential so far as schedular benefits are concerned. The concept of the manufacturing license is the most viable approach for DOD to follow if it were to participate in the licensing process. When coupled with the concept of a pre-approved site, the maximum benefits possible under the current regulatory policy would accrue. Additional licensing schedular gains could be realized if a review plan such as outlined in NUREG-0292 (3.6) were followed.

The licensing process that is foreseen should these two concepts be used with a NUREG-0292-type review is as follows:

1. DOD selects a contractor who then applies to the NRC for a manufacturing license under Appendix M to 10 CFR Part 50. This manufacturing license, under current NRC policy, would allow the production of ten reactors within a five-year peirod.

2. DOD selects a site for each of the ten units to be produced under the manufacturing license.

3. DOD and its contractors meet with the appropriate members of the NRC staff regarding each of the early site reviews, and the forthcoming construction permit applications.

4. DOD, on its own, or through appropriate contractors, prepares an early site review application (Environmental Report and site suitability information) for each site.

5. DOD submits the early site review applications to NRC for review. The early site review of site suitability issues is based on an enveloping approach. This enveloping approach eliminates the necessity of having the design details of the specific nuclear power plant proposed for the site available at the time the review is performed. But the proposed design would have to fall within the acceptable envelope for each early reviewed site.

6. NRC issues Draft and Final Environmental Statements.

7. Public hearing on site suitability issues.

8. ASLB decision on site suitability for each site.

9. DOD contractor obtains manufacturing license from NRC.

10. DOD prepares a application for each reactor unit covered by the manufacturing license to be located at one of the pre-approved sites (PSAR only needs to address plant-site interfaces). Because of its very nature, DOD may have a legal exemption from anti-trust review, even if it elects to pursue an operating license from the NRC.

11. DOD submits the PSAR to the NRC.

12. NRC performs acceptance review of each PSAR.

13. NRC transmits acceptance review results to DOD for each application.

14. NRC staff prepares each draft SER.

15. DOD-NRC meetings to resolve areas of concern for each review.

16. NRC prepares and issues each SER.

17. ACRS Subcommittee meeting for each application.

18. ACRS Committee meeting for each application.

19. NRC staff issues each SER supplement.

20. Public hearings for each application, only regarding safety matters limited to plant-site interfaces.

21. ASLB decision on each construction permit.

22. NRC issues each construction permit.

23. DOD contractor submits final design of reactor to NRC in form of an application for amendment of the manufacturing license.

24. NRC issues amendment to manufacturing license.

25. DOD-NRC pre-application meetings.

26. DOD prepares an FSAR and updated ER for each reactor produced under manufacturing license coupled with each pre-approved site - only need to address plant-site interfaces.

27. DOD submits FSAR and updated ER to NRC.

28. NRC performs acceptance review of each FSAR and ER.

29. through 37 - same as 6 plus 13 through 21 (assumes no environmental hearing).

38. NRC issues operating license for each plant.

To date, the NRC has only received one application for a manufacturing license, which is the Offshore Power Systems application for a license to manufacture a series of floating nuclear power plants (3.16). Since the licensing review of that application has encountered problems which may be unique to the proposed design (e.g., liquid pathway following a core melt accident, detonation of a loaded munitions vessel, fire from a grounded fuel tanker), the review schedule has incurred a number of long delays. Consequently, the review schedule for that application cannot be taken as typical of a manufacturing license review. Based on the discussion of the manufacturing license review in NUREG-0427 (3.7), it seems more reasonable to assume that the review schedule and corresponding level of effort required to support a manufacturing licensing review would be about the same as those associated with a construction permit review. Table 3-3 shows the schedule and level of effort that a DOD contractor would

experience for the manufacturing license review. The manufacturing license review strategy is assumed to use the pre-application meetings and draft SER approach advocated in NUREG-0292 (3.6) to shorten the licensing review. With this approach, formal rounds of questions are eliminated and replaced by a series of technical meetings between the applicant and the NRC staff reviewers. Soon after the application is docketed by the NRC, the NRC staff prepares a draft SER. If the applicant has properly responded to concerns voiced by NRC reviewers during the pre-application phase, preparation of the draft SER should be facilitated. Following issuance of the draft SER, the applicant and the NRC staff attempt to resolve all outstanding issues within the context of technical meetings. If all goes as planned, about six months after docketing of the application, the final SER can be issued. The rest of the review is essentially unchanged from the conventional licensing review. The environmental review for a manufacturing license evaluates the impact of the manufacturing facility on its environs.

Table 3-4 shows the estimated schedule and level of effort required to support the early site review for each of the ten sites chosen for a reactor unit covered by the manufacturing license.

Table 3-5 indicates the estimated schedule and level of effort involved in supporting a construction permit review which references the reactor design covered by the manufacturing license and a pre-approved site.

Before the manufacturing license could be used with an operating license application, the manufacturing license holder would have to submit the final reactor design to the NRC in an application for an amendment to the manufacturing license. Then DOD could submit operating license applications which

referenced the final design covered by the amended manufacturing license and each of the pre-approved sites. To date, no manufacturing license has been issued by the NRC. Therefore, no data exist on the schedule required for the NRC review of an application to amend such a license. As a rough estimate, it was assumed that the schedule and level of effort required to support the final design review of an application to the manufacturing license would be comparable to the original manufacturing license review. For this case, Table 3-3 would also be applicable. The schedule and level of effort required to support the review of ten operating license applications using the final design covered by the amended manufacturing license and the pre-approved sites would be similar to the construction permit review data shown in Table 3-5. Additional time and effort would be needed to prepare the Technical Specifications. However, if no hearing were required, the total effort would be unchanged from Table 3-5. To this must be added the time and effort needed to prepare an environmental report. The significant savings in schedule time and effort in the approach described herein are realized in that the reactor design for the DOD facility would only have to be reviewed once for each ten units. Each of the ten sites would have to be reviewed individually, as would the plant/site interfaces for each case. In summary, two manufacturing license reviews, ten early site reviews, ten construction permit reviews, and ten operating license reviews would be needed to implement this approach.

The degree of complexity in implementing the use of a manufacturing license might be reduced somewhat if DOD were to meet with NRC prior to embarking on such a task. The purpose of this meeting would be explore avenues that might be available to handle some or all of the multiple reviews on a generic basis.

TABLE 3-1

SUPPORT REQUIRED FOR CONSTRUCTION PERMIT REVIEW PHASE

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| Prepare PSAR for Acceptance Review | 21 | 93-110 |
| Prepare QA Manual for Acceptance Review | 12 | 51-62 |
| Prepare Env. Report for Acceptance Review | 12 | 51-62 |
| Preparation of Antitrust Info. | 9 | 40-46 |
| Prepare Responses to Acceptance Review Questions | 2 | 8-10 |
| Prepare Responses to First Round Questions | 2 | 8-10 |
| Prepare Responses to NRC Staff Positions | 2 | 8-10 |
| Prepare for ACRS Subcommittee Mtg. | 2 | 8-10 |
| Prepare for ACRS Committee Mtg. | 0.5 | 2-3 |
| Prepare Responses to NRC Staff SER | 3 | 13-15 |
| Prepare Responses to NRC Staff SER Supplement | 2 | 8-10 |
| Prepare Testimony for Env. Hearing | 1 | 4-5 |
| Prepare Testimony for Safety Hearing | 1.5 | 6-7 |
| Total | | 300-360 |

*Additional effort only required because of the licensing process.

TABLE 3-2

SUPPORT REQUIRED FOR OPERATING LICENSE REVIEW PHASE

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| Prepare FSAR for Acceptance Review | 21 | 120-140 |
| Prepare Env. Report for Acceptance Review | 12 | 68-82 |
| Prepare Responses to Acceptance Review Questions | 2 | 11-14 |
| Prepare Responses to First Round Questions | 2 | 11-14 |
| Prepare Responses to NRC Staff Positions | 2 | 11-14 |
| Prepare for ACRS Subcommittee Mtg. | 2 | 11-14 |
| Prepare for ACRS Committee Mtg. | 0.5 | 3-4 |
| Prepare Responses to NRC Staff SER | 3 | 17-20 |
| Prepare Responses to NRC Staff SER Supplement | 1 | 6-7 |
| Prepare Testimony for Safety Hearing | 1.5 | 8-10 |
| Prepare Technical Specifications | 6 | 34-41 |
| Total | | 300-360 |

*Additional effort only required because of the licensing process.

TABLE 3-3

ESTIMATED SCHEDULE AND LEVEL OF EFFORT
REQUIRED TO SUPPORT MANUFACTURING LICENSE REVIEW

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| DOD Contractor Prepares First Draft of PSAR | 21 | 41-55 |
| DOD Contractor Prepares Env. Report | 12 | 51-62 |
| DOD Contractor Prepares Financial Information | 9 | 8-10 |
| DOD Contractor Holds Pre-application Mtgs. with NRC Staff and Modifies PSAR Accordingly | 12 | 42-55 |
| DOD Contractor Meets with NRC Staff to Resolve Issues Raised in Draft SER | 6 | 47-58 |
| Prepare for ACRS Subcommittee Mtg. | 2 | 8-10 |
| Prepare for ACRS Committee Mtg. | 0.5 | 2-3 |
| Prepare Responses to SER | 3 | 13-15 |
| Prepare Responses to SER Supplement | 1 | 8-10 |
| Prepare Testimony for Env. Hearing | 1 | 4-5 |
| Prepare Testimony for Safety Hearing | 1.5 | 6-7 |
| Total | | 230-290 |

*Additional effort only required because of the licensing process.

TABLE 3-4

ESTIMATED SCHEDULE AND LEVEL OF EFFORT
REQUIRED TO SUPPORT EARLY SITE REVIEW

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months |
|---|---|---|
| DOD Meetings with NRC to Discuss Environmental and Site Suitability Matters | 12 | 25-31 |
| DOD Prepares Env. Report and Site Suitability Information | 12 | 36-31 |
| DOD Meets with NRC to Resolve Env. and Site Issues | 6 | 5-10 |
| Preparation of Testimony for Env. and Site Suitability Hearing | 1 | 4-5 |
| Total | | 70-77 |

*Additional effort only required because of the licensing process.

TABLE 3-5

ESTIMATED SCHEDULE AND LEVEL OF EFFORT REQUIRED TO SUPPORT MODIFIED CONSTRUCTION PERMIT REVIEW

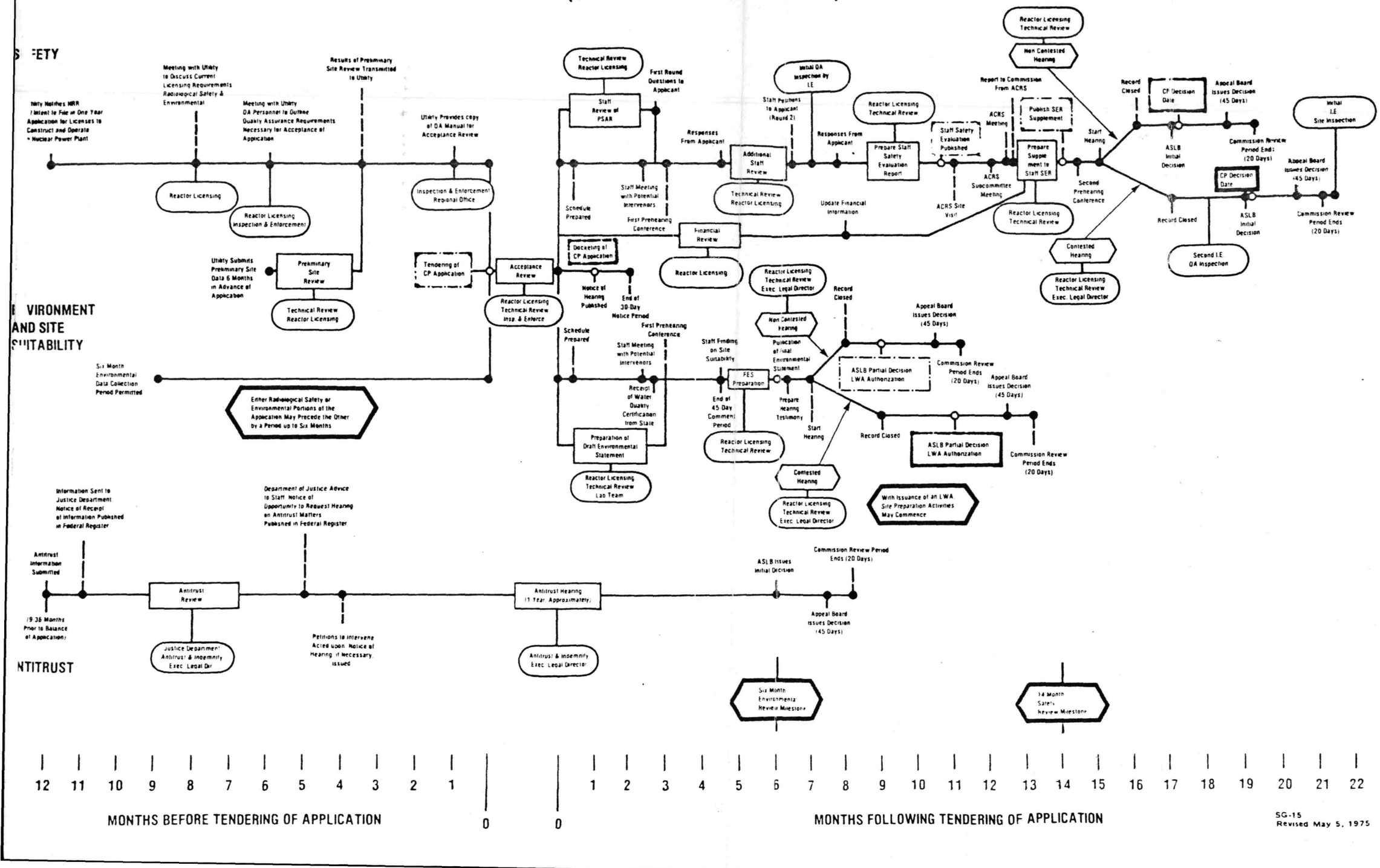
| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| DOD Prepares Draft PSAR Referencing Reactor Design Covered by Manufacturing License and Pre-approved site | 9 | 46-55 |
| DOD Holds Pre-Application Meetings with NRC to Discuss Plant/Site Interfaces and Modifies PSAR Accordingly | 12 | 47-55 |
| DOD Prepares QA Manual | 12 | 51-62 |
| DOD Meets with NRC to Resolve Draft SER Issues | 6 | 45-55 |
| Prepare for ACRS Subcommittee Mtg. | 2 | 8-10 |
| Prepare for ACRS Committee Mtg. | 0.5 | 2-3 |
| Prepares Responses to NRC Staff SER | 3 | 13-15 |
| Prepare Responses to NRC Staff SER Supplement | 2 | 8-10 |
| Prepare Testimony for Safety Hearing | 1.5 | 6-7 |
| Total | | 226-272 |

*Additional effort only required because of the licensing process.

Figure 3-1 (Taken from Reference 3-5)

# NUCLEAR POWER PLANT LICENSING PROCESS

## (CONSTRUCTION PERMIT)

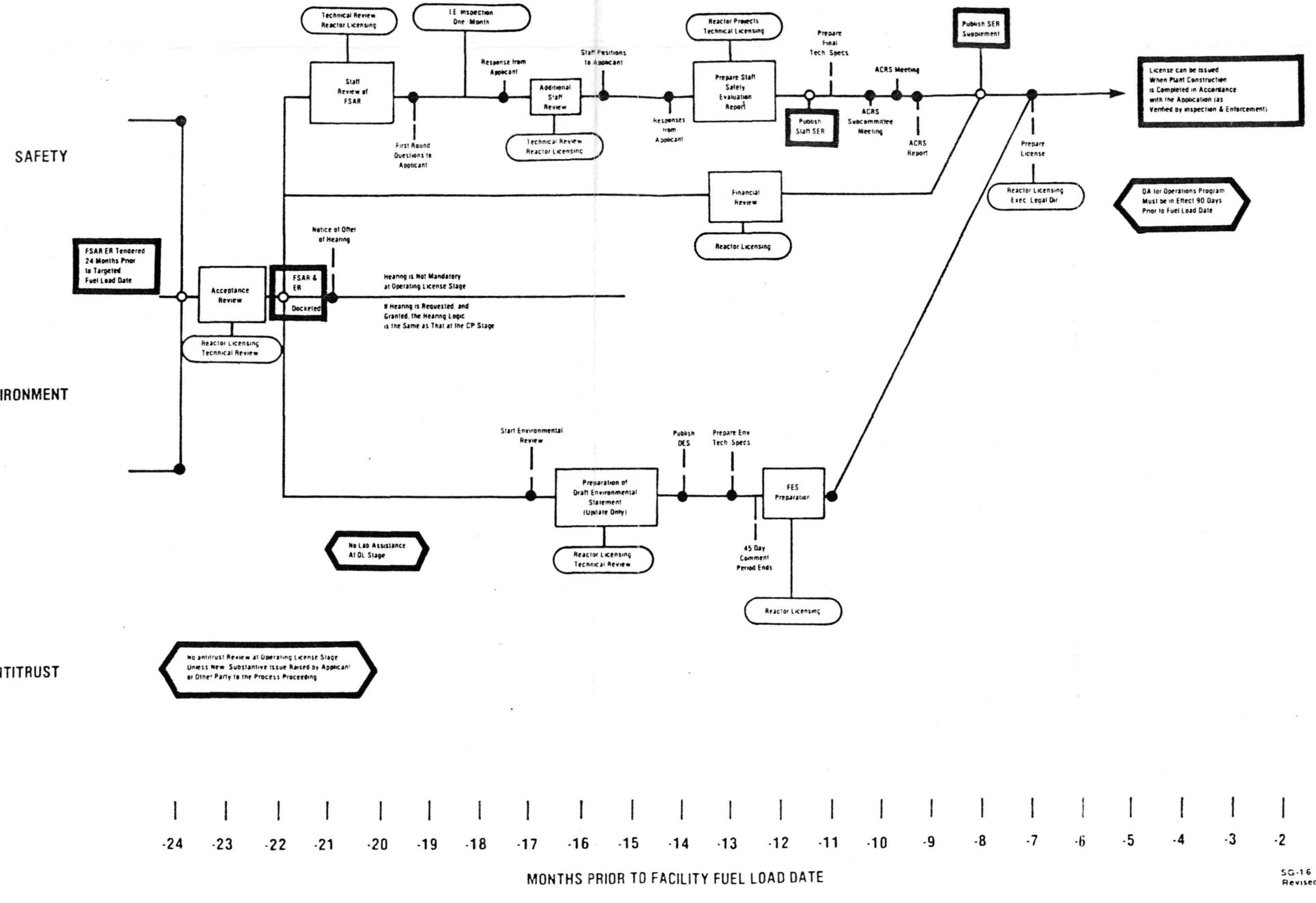



SG-15
Revised May 5, 1975

Figure 3-2 (Taken from Reference 3-5)

# NUCLEAR POWER PLANT LICENSING PROCESS

## (OPERATING LICENSE)



# 4.0 RADIOISOTOPIC THERMOELECTRIC AND DYNAMIC ELECTRIC GENERATORS WITH SR-90 OR PU-238

## 4.1 Applicable Regulations

NRC licensing of both radioisotopic thermoelectric generators and dynamic electric generators (which are referred to as radioisotopic power generators or as devices) would be governed by the rules of Title 10, Code of Federal Regulation (10 CFR), Parts 20, 30, 51, 70, 71, 73, 75, and 170. These regulations cover the following general areas:

Part 20: Radiation protection

Part 30: Licensing of byproduct material (Sr-90)

According to Section 2009 of the Atomic Energy Act, byproduct material is defined as "(1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, or (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content."

Part 51: Environmental protection

Part 70: Licensing of special nuclear material (Pu-238)

According to Section 2031 of the Atomic Energy Act, special nuclear material is defined as "(1) plutonium, uranium enriched in the isotope 233 or in the isotope 235, and other material which the Commission, pursuant to the provisions of Section 51, determines to be special nuclear material, but does not include source material; or (2) any material artifically enriched by any of the foregoing, but does not include source material."

Part 71: Packaging and transportation of radioactive material

Part 73: Physical protection of materials

Part 75: Safeguards for special nuclear material

Part 170: Fees for licensing reviews

## 4.2 Regulatory Guides

Regulatory Guide 6.3, "Design, Construction, and Use of Radioisotopic Power Generators for Certain Land and Sea Applications" (4.1), reproduced in Appendix A, provides additional licensing guidance. Regulatory Guide 6.3 makes extensive reference to the International Atomic Energy Agency (IAEA) Safety Series No. 33, "Guide to the Safe Design, Construction and Use of Radioisotopic Power Generators for Certain Land and Sea Applications" (4.2). The NRC former (AEC) has not reviewed radioisotopic power generators using large amounts of byproduct or special nuclear material for several years, and might wish to update the regulations and guidance prior to conducting a licensing review.

## 4.3 Standard Format and Content (Information Submittal Requirements)

The NRC has recently updated guidelines for applications for registration of sealed sources and devices containing radioactive material (Appendixes B and C) (4.3, 4.4). While these guidelines were intended mainly for smaller scale uses of radioisotopes, the type of information required to review radioisotopic power generators would be similar. These guidelines reference American National Standards Institute (ANSI) standards which, again, are generally written to be applicable to small scale uses of radioisotopes.

## 4.4 Possible Licensing Process for Radioisotopic Power Generators

### 4.4.1 Preliminary Discussion with the Director of the NRC Office of Nuclear Material Safety and Safeguards

The estimated size and number of radioisotopic power generators should be discussed. NRC would probably review existing requirements and update them if it were thought to be necessary. Proposed designs and licensability should be discussed.

### 4.4.2 DOD Selects a Manufacturer(s)

The manufacturer would apply for a manufacturing license from the NRC. Title 10, Code of Federal Regulations, Part 30 would apply for byproduct material (Sr-90) and Part 70 for special nuclear material (Pu-238). The safeguards requirements of Part 75 would apply for special nuclear material. Both the device and the manufacturing facility would have to meet the

radiation protection requirements of 10 CFR Part 20. The manufacturer would have to demonstrate compliance with the physical protection of materials requirements of 10 CFR Part 73. The manufacturer would also have to pay NRC a licensing fee according to 10 CFR Part 170. Depending on the amount of radioisotopic material involved, the design of the manufacturing process, and the design of the device, an environmental impact statement (10 CFR Part 51) might be required. Currently, most manufacturing of radioisotopic sources has not required an environmental impact statement. The NRC does not usually hold public hearings in the radioisotopic licensing process. A manufacturer would have to meet state and local requirements. State involvement would be greater for a manufacturing site in an NRC agreement state, with NRC's involvement being reduced by an equivalent amount. Upon completion of the licensing review, the NRC would issue a Safety Evaluation Report containing the basis for licensing.

### 4.4.3 Transportation to the Site

The NRC is responsible for licensing the packaging of radioactive material for transportation under 10 CFR Part 71. The actual transportation is regulated by the Department of Transportation (DOT) in 49 CFR Parts 170-189, and by state and local governmental requirements. NRC provides enforcement of the DOT regulations.

### 4.4.4 Licensing of the User

The NRC would also license the receiver and user (DOD facility) of radioisotopic power generators under 10 CFR Parts 30 and 70. The NRC would apply 10 CFR Part 20 for radiation protection and operator training, and 10 CFR Part 75 for

safeguards of special nuclear material. The need for licensing the user depends on the amount of radioactive material and radiation hazard of the device (the users of smoke detectors are not licensed). No environmental impact statement would be necessary unless the design of the device allows for the potential of environmental impact beyond the site. The NRC would issue a Safety Evaluation Report containing the basis for licensing.

### 4.4.5 Post-Licensing Inspections

Holders of NRC licenses are subject to inspections by NRC's Office of Inspection and Enforcement. The frequency of these inspections will depend on the NRC-perceived hazard associated with the operation of the particular radioisotopic power generators.

### 4.4.6 Decommissioning

Under the conditions of 10 CFR Part 30 and 10 CFR Part 70 licenses, the NRC would have to approve the transfer of radioisotopic material from the user to another facility (even if the receiving facility is licensed). During the manufacturer licensing and user licensing reviews, the NRC would probably request information on recovery or replacement of the radioactive fuel capsule at the conclusion of its useful life. Additional discussion on disposal after use is contained in Section 2.10 of IAEA Safety Series No. 33, "Guide to the Safe Design, Construction and Use of Radioisotopic Power Generators for Certain Land and Sea Applications" (4.2).

## 4.5 Schedule and Level of Effort to Support NRC Licensing

The NRC licensing process for radioisotopic power generators is considerably less complex than the reactor licensing process. Rather than the two-step construction and operational license reviews for reactors, the licensing of radioisotopic power generators is closer to a one-step license review, resulting in only an operational license. Depending on the size and number of devices to be produced, an environmental impact statement and public hearings may not be necessary.

Table 4-1 estimates the schedular and level-of-effort ranges to support the licensing process. The estimates assume production of 20 devices, each with a useful life of 10 years. These estimates are based on discussions with the NRC and on the judgement of NUS Corporation personnel (4.5). There is no recent experience in licensing radioisotopic power generators, and NRC would probably reconsider its ten-year-old licensing requirements upon receipt of an application. These estimates should therefore be considered rough estimates.

If the manufacturer selected already has an NRC license, the licensing cost would be somewhat lower. A licensed manufacturer would already have an approved quality assurance program, approved emergency procedures, and may already be licensed to handle the amount of radioactive material involved. The NRC then would only have to review the design and radiological safety of the proposed device. The use of a design containing a critical amount of special nuclear material would require some additional effort to demonstrate the safety of the device.

TABLE 4-1

SCHEDULE AND LEVEL OF EFFORT TO SUPPORT
NRC LICENSING OF RADIOISOTOPIC POWER GENERATORS

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| Preliminary Design Information and Discussion with the Director of NMSS | 3-6 | 1 |
| Manufacturer Prepares Safety Analysis Report for NRC Review and Provides Information Until License is Obtained | 12-24 | 15-24 |
| Environmental Impact Statement if Required | 3-9 | 7-10 |
| State and Local Regulatory Requirements | 12-24 | 3-6 |
| User Prepares a Safety Analysis Report Concerning the Site, Radiation Protection, Training, and any Site-device Interfaces. Additional Information is Provided Until License is Obtained. | 3-9 | 6-18 |
| Post-Licensing<br><br>Interfacing with NRC Inspectors, and Meeting Reporting Requirements | One-half Month/Year/ Device | 100** |
| Total | | 132-159 |

*Additional effort only required because of the licensing process.

**Assumes 20 devices with a 10-year useful life.

## 5.0 APPLICATIONS OF RADIOISOTOPES FOR LUMINOUS SOURCES (LIGHTS) WITH H-3, KR-85, PM-147

This section contains an update to an earlier study done for the U. S. Department of Energy by NUS Corporation, "Review of NRC Licensing Requirements and Their Impact on the Development and Testing of the Kr-85 Runway Light," NUS-3666, September 1980 (5.1). The study has been updated to include changes necessary to accommodate the licensing of H-3, Kr-85, and Pm-147 luminous sources. The attachments have been updated with the latest material. Section 5.5 is new and contains a discussion of the schedule and level of effort required to support NRC's review.

### 5.1 Introduction

The design, manufacture, distribution, and use of most devices containing radioactive (byproduct) materials are regulated by the Federal government, through the U. S. Nuclear Regulatory Commission, or by the states on behalf of the Federal government, through the NRC's Agreement States Program. (Transportation of radioactive materials is regulated by the U. S. Department of Transportation.) The principal exception to the NRC and state regulation of byproduct materials is the statutory exclusion of the Department of Defense, the Department of Energy, and DOD, DOE, and NRC contractor activities (a) on Federally owned lands, (b) in the interest of national defense, or (c) specifically exempted by the NRC in the public interest. To evaluate the potential influence of NRC licensing requirements on design, testing, and licensability of H-3, Kr-85, and Pm-147 for luminous sources, NUS reviewed the current regulations, guidance, and practices of the NRC that

bear on certification of new devices containing radioactive materials. The results of this review are presented below.

## 5.2 Applicable Regulations

Nuclear Regulatory Commission certification of byproduct material applications is governed by the rules of Title 10, Code of Federal Regulations, Parts 30 through 35 (10 CFR 30-35). Most of the regulations, like most of the radioisotope applications, are directed at the use of small (millicurie) quantities of activity per device, rather than large (multicurie) quantities.

NRC issues two types of licenses for byproduct material: general and specific. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in Parts 30-35. General licenses are effective without the filing of applications with the NRC or the issuance of licensing documents to particular persons. Under Section 31.5, the NRC issues a general license permitting anyone to receive, possess, use, or transfer byproduct material contained in, among other things, "devices designed and manufactured for...producing light," provided the devices have been manufactured and initially transferred in accordance with a specific license issued pursuant to Section 32.51, or the equivalent requirements of an Agreement State. Section 32.51 defines the requirements for NRC issuance of a specific license to manufacture or initially transfer devices containing byproduct materials for use under Section 31.5.

Among the specific requirements of Section 32.51 are the following:

- o 30.33(a)(2) (by reference) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property.

- o 30.33(a)(3) (by reference) The applicant is qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property.

- o 32.51(a)(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality controls, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

  (i) The device can be safely operated by persons not having training in radiological protection.

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any calendar quarter a dose exceeding 10 percent of the limits specified in Section 20.101 (i.e., 10 percent of 1.25 rem/quarter for whole body, 18.75 rem/quarter for extremities, 7.5 rem/quarter for skin).

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment exceeding 15 rem whole body, 200 rem to the extremities and skin, and 50 rem to other organs.

- 32.51(b) If the applicant desires that the device be required to be tested for proper operation and for leakage at intervals longer than six months,

he must submit additional information for the Commission's consideration on:

1. Primary containment (source capsule)

2. Protection of primary containment

3. Method of sealing containment

4. Containment construction materials

5. Form, quantity, and radiotoxicity of contained radioactive materials

6. Maximum temperature and pressure withstood during prototype test

7. Operating experience with similar devices

Transportation requirements for radioactive materials are determined by the Department of Transportation (DOT) and adopted by the NRC. State laws and regulations and local ordinances may put additional requirements on shipments and shippers of radioactive materials. The variation among these

additional requirements does not permit their summary here. However, they should be examined when specific manufacturing sites, distribution or storage sites, and use sites are identified. The NRC has recently compiled state laws and regulations on the transport of radioactive materials in NUREG/CR-1263 (5.2).

## 5.3 Regulatory Guides

To expand on the regulations or to offer an example of an acceptable way to meet the regulations, NRC issues Regulatory Guides. Regulatory Guide 10.7 (5.3), included as Appendix D, describes the type of information the NRC requires for licensing of devices using byproduct material. Regulatory Guide 6.4 (5.4), included as Appendix E, provides additional information on containment properties of radioactive sources in devices distributed under a general license. Specifically, this Guide endorses ANSI Standards N540-1975 and N542-1977 (5.5, 5.6). The information in the standards bears directly on the design and the prototype testing program for radioactive self-luminous light sources and sealed radioactive sources.

NRC also has two internal documents on the standard format and content of applications for review of sealed sources and devices containing radioactive materials, respectively (4.3, 4.4). These are reproduced as Appendices B and C.

## 5.4 NRC Review

An applicant for an NRC license to manufacture the light must submit design, testing, and use data according to the guidelines of the Standard Format and Content (4.3, 4.4). The

prototype testing program must encompass the performance standards of ANSI-N540 (or ANSI N542, if each light contains more than 30 curies). The Standard Format and Content alludes to quality control requirements. More information on quality assurance and control requirements is found in Appendix B of ANSI-N542. The applicant must also submit a safety analysis demonstrating that, under ordinary conditions of handling, storage, and use of the device, the radioactive contents will not be released and that it is unlikely anyone will receive exposures greater than 0.5 rem whole body, 7.5 rem to the skin and extremities, and 3 rem to other organs, per year. This could bear on shielding requirements. Furthermore, the safety analysis must show that, under accident conditions, it is unlikely that anyone would receive exposures greater than 15 rem whole body, 200 rem to the skin and extremities, and 50 rem to other organs. The safety analysis must also indicate how the device can be tested, serviced, installed, and operated without jeopardizing human health.

A private firm seeking a manufacturing license must also demonstrate that its proposed facilities and equipment are adequate to protect the public. This would include a description of radiological effluent controls and demonstration that its organization and staff are qualified by training and experience to handle the material for the purpose requested without endangering the public health and safety.

Application for NRC materials licenses must be accompanied by a fee, as prescribed by 10 CFR 170.

Usually, no environmental impact statement or public hearings would be required. As specifed in 10 CFR 30.15, users of small quantities of radioactive material would be exempt from licensing.

## 5.5 Schedule and Level of Effort to Support an NRC Review

Table 5-1 estimates the schedular and level-of-effort ranges to support the licensing of radioactive self-luminous light sources. The estimates are for one-device design and assume manufacture of a large number of the devices. The device life is assumed to be 10 years. Since the NRC issues a license which is valid for a period of 5 years, the user would have to process one license renewal. The renewal requires an update of perviously submitted information. If the information has not changed, the licensing effort is minor.

The Table 5-1 estimates are based on discussions with the NRC and on the judgement of NUS Corporation personnel (4.5). Recent experience has shown that it takes the NRC three to six months to approve a radioisotopic license. The amount of review time depends on the quality of information in the license applciation, the amount of radioactive material involved (hazard associated with the device), and whether the manufacturer already has a license.

TABLE 5-1

SCHEDULE AND LEVEL OF EFFORT TO SUPPORT
NRC LICENSING OF RADIOISOTOPES FOR
LUMINOUS SOURCES

| Action | Schedule (Months) | Incremental Level of Effort* (Man-Months) |
|---|---|---|
| Manufacturer Prepares Safety Analysis Report for NRC Review | 3-6 | 6-12 |
| User Prepares Safety Analysis Report Concerning Training, Radiation Protection, and Handling of Quantities of the Devices | 2-4 | 4-8 |
| Post-Licensing Interfacing, Reporting Requirements, and License Renewals | 2 Days/Year Reporting Requirements; One half Man-Month in 5 years Renewal Paperwork | 1.5** |
| Total | | 11.5-21.5 |

*Additional effort only required because of the licensing process.

**Assumes 10 yr Source Life

# 6.0 OTHER OPTIONS AVAILABLE TO DOD

## 6.1 Independent Nonlicensing Review by NRC

The study examines the NRC licensing process and the schedular and level-of-effort impact if DOD chooses to use the complete process. Under the Atomic Energy Act of 1954, DOD and its prime contractors are exempt from NRC's licensing requirements. Obtaining licenses for nuclear power reactors and uses of radioisotopes would be a voluntary action by DOD. In the case of nuclear power reactors, a rather complex technology, the licensing process is lengthy and costly in time spent interfacing with the regulators. For radioisotopic thermal-electric and dynamic electric generators, the licensing process is much easier and less costly. The licensing requirements for radioisotopic power generators are, however, ten years old and, therefore, will probably be updated by the NRC upon receipt of an application. The licensing of radioactive self-luminous light sources is fairly well defined and the incremental licensing effort less costly than for reactors and radioisotopic power generators. Certainly, avoiding a licensing review would save a considerable amount of time and money; the licensing process does, however, provide an independent safety review and public health and safety review as well as design review and environmental impact considerations that could provide important additional assurance for DOD.

DOD could choose to exercise its exemption from licensing, but could ask for an independent review from NRC. This would save some of the paperwork associated with the licensing process, but would still allow for independent review of the use of nuclear energy. This would also provide relief from the

particularly costly public participation and the post-licensing requirements of reporting, inspection, and relicensing. In areas of classified uses of nuclear energy, the licensing process is too open to maintain appropriate security, but NRC could maintain appropriate security in an independent nonlicensing review.

Indeed, NRC has already done many independent nonlicensing reviews for DOD, DOE and the U. S. Maritime Administration, including Naval Reactors, the Consolidated Nuclear Steam Generator (CNSG) (for the U. S. Maritime Administration), the Fast Flux Test Facility, test reactors, and uses of radio-isotopes.

### 6.1.1 Naval Reactors

Based on a request by President Kennedy, the NRC (former AEC) provides assistance to DOD on nuclear safety. The NRC's review of naval reactors is done on a classified basis. The Navy provides a Safety Analysis Report (SAR) asking for NRC's advice. NRC's review is not a licensing review but rather a review that provides suggestions and assistance. The NRC review does result in a Safety Evaluation Report (SER) that is reviewed by the Advisory Committee on Reactor Safeguards (ACRS) in a meeting closed to the public. Typically, the NRC does a complete review on a totally new design or concentrates on new and unique areas of already reviewed designs that have been modified. (6.1)

### 6.1.2 Consolidated Nuclear Steam Generator

During the mid-1970's, the NRC (former AEC) reviewed the Consolidated Nuclear Steam Generator (CNSG) power plant design for the U. S. Maritime Administration (MarAd). The power

plant was to be used for propulsion of ships of the U. S. merchant marine fleet. The CNSG is a relatively compact reactor power plant with the entire primary system (except pressurizer) located inside the primary vessel. This compact design could also have some advantages for land-based, small-to-medium-sized reactors for DOD use. These advantages include maximum factory fabrication, reduced site construction time, primary system placement in one lift, and easier quality control.

The NRC conducted a thorough review of the CNSG to the draft Safety Evaluation Report stage. The review included consideration of ship accidents and sinking, as well as reactor system safety. The review was stopped before completion, because of the low price of oil and the lack of interest in using the CNSG for a merchant ship by private companies, and the Safety Evaluation Report was not formally reviewed by the Advisor Committee on Reactor Safeguards (6.2).

As outlined in Section 3.0, today's licensing review by NRC is much more rigorous and how the CNSG design would fare under today's licensing requirements is unknown. Certainly loss-of-coolant accident (LOCA) loads on containment and fire protection might require additional analysis and design changes.

### 6.1.3 Fast Flux Test Facility

The Fast Flux Test Facility (FFTF) is a sodium-cooled fast spectrum experimental reactor owned by the Federal Government. The Department of Energy has authority for the operation of the FFTF and the Department's FFTF Project Office in Richland, Washington, is responsible for its safe operation. The NRC, upon request of the Department of Energy, provided advice

regarding safety issues and the adequacy of the FFTF design, in accordance with provisions of the Energy Research and Development Administration-Commission interagency agreement for the performance of safety reviews for reactors exempt from licensing.

Advice regarding the FFTF was requested by the Energy Research and Development Administration, now the Department of Energy, through the FFTF Project Office in a letter dated November 13, 1975. This request followed an earlier review of the FFTF preliminary design performed by the former-Atomic Energy Commission's Regulatory Staff at the request of the AEC's Division of Reactor Development and Technology.

The scope of the review requested by DOE was defined by the letter from R. L. Ferguson to R. P. Denise, dated August 20, 1976 (6.3). The scope of the review was later modified by the letter of July 14, 1977, from R. L. Ferguson to R. P. Denise(6.4), which advised the NRC that it was not necessary for it to review the FFTF safeguards and security provisions.

The objective of the NRC's review was to provide an in-depth technical review of the design of the FFTF comparable to that of a licensed plant. Site-related matters were considered to have been adequately reviewed during the construction phase and were not re-reviewed. An in-depth review was not requested but NRC comments were specifically solicited in the following areas:

1. Operations

2. Startup testing

3. Quality assurance

4. Technical Specifications

DOE submitted an FSAR for review by the NRC staff. After a number of meetings with DOE and rounds of questions, the NRC staff issued a Safety Evaluation Report and a supplement to the SER. The ACRS also performed an independent review of FFTF and documented the results of that review in a letter to the Chairman of the NRC.

The nature of the FFTF safety review by the NRC was advisory only and did not involve the issuance of an operating license. The review was directed towards evaluating the adequacy of the design to ensure safe operation of the plant. The Department of Energy has a discretionary option of following the NRC's advice and has the final responsibility for the design and safe operation of the FFTF. The NRC did not provide inspection enforcement support during the construction of the FFTF, nor is it involved in its operation under the existing interagency agreement.

## 6.2 DOE Coordination of NRC Licensing for DOD

DOE could provide coordination of the design and licensing of DOD uses of nuclear energy. The advantage to DOD would be capitalizing on the experience of DOE, both in design/contractor coordination and in experience with the NRC licensing progress (Clinch River). This could be a very logical option because DOE already handles most uses of nuclear energy for DOD.

The costs of getting through the licensing process would be the same as discussed above and in the study.

## 6.3 Use of the Interagency Nuclear Safety Review Panel (INSRP) Process

Another possible option open to DOD is using a safety review process similar to the process currently being used for space nuclear energy sources (6.1). In this process, the NRC is involved only as an observer. The process is not a licensing process, but rather a very thorough safety review process.

The Interagency Nuclear Safety Review Panel (INSRP) is a panel chaired by coordinators appointed by DOD, DOE, and NASA. For terrestrial uses of nuclear energy, NASA could possibly be replaced by NRC and EPA. The INSRP coordinates the review (evaluations, calculations, tests) of a Safety Analysis Report submitted by the nuclear energy source developer. The INSRP coordinators issue an independent nuclear risk assessment in the form of a Safety Evaluation Report. The recommendation for final approval of the use of nuclear energy would rest on the overall risk-benefit evaluation by DOD, DOE, NRC, and EPA.

## 7.0 REFERENCES


1.1 "The Licensing of Power Plants in the United States," Arthur W. Murphy, D. Bruce La Pierre, Neil Orloff, Seven Springs Center, Yale University, January 1978.

1.2 "Cost Impacts Related to Nuclear Power Plant Project Duration," Subcommittee on Financing the Nuclear Fuel Cycle of the Committee on Financial Considerations, Atomic Industrial Forum, Inc., April 1978.

1.3 "Licensing, Design and Construction Problems: Priorities for Solution," Review Group on Design and Construction Project Leadtimes, Atomic Industrial Forum, Inc., January 1978.

3.1 Preamble to Regulatory Guide Series, Directorate of Regulatory Standards, U. S. Atomic Energy Commission, December 12, 1972.

3.2 "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition," Regulatory Guide 1.70, Revision 3, Office of Standards Development, U. S. Nuclear Regulatory Commission, November 1978.

3.3 "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants - LWR Edition," NUREG-0880, Office of Nuclear Reactor Regulation, July 1981.

3.4 "The Reactor Licensing Process," Office of Public Affairs, Region I, U. S. Nuclear Regulatory Commission, January 25, 1979.

3.5 "Licensing Project Manager's Handbook," U. S. Nuclear Regulatory Commission, May 1, 1975.

3.6 "Nuclear Power Plant Licensing: Opportunities for Improvement," NUREG-0292, U. S. Nuclear Regulatory Commission, June 1977.

3.7 "Review of the Commission Program for Standardization of Nuclear Power Plants and Recommendations to Improve Standardization Concepts," NUREG-0427, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, May 1978.

3.8 "Nuclear Power Plants, Construction Status Report," NUREG-0030, Vol. 6, No. 1, U. S. Nuclear Regulatory Commission, June 1982.

3.9 "Regulatory Licensing, Status Summary Report," NUREG-0580, Vol. 11, No. 8, U.S. Nuclear Regulatory Commission, August 1982.

3.10 Personal communications between P. D. O'Reilly (NUS) and W. Kane, Office of Nuclear Regulation, (USNRC), September 7-8, 1982.

3.11 Personal communication between P. D. O'Reilly (NUS) and P. Higgins (Atomic Industrial Forum), September 7, 1982.

3.12 "Cost Impacts Related to Nuclear Power Plant Project Durations," Subcommittee on Financing the Nuclear Fuel Cycle of the Committee on Financial Considerations, Atomic Industrial Forum, Inc., April 1978.

3.13 "The Licensing of Power Plants in the United States," Arthur W. Murphy, A. Bruce La Pierre, and Neil Orloff, Seven Springs Center, Yale University, January 1978.

3.14 "Expediting the Licensing Review Process," D. L. Nordstrom, Licensing Information Service, NUS Corporation, September 1981.

3.15 "Licensing, Design, and Construction Problems: Priorities for Solution," Review Group on Design and Construction Project Lead Times, Atomic Industrial Forum, Inc., January 1978.

3.16 U. S. Nuclear Regulatory Commission Docket No. STN 50-437, application docketed May 7, 1973.

4.1 "Design, Construction, and Use of Radioisotopic Power Generators for Certain Land and Sea Applications," Regulatory Guide 6.3, U. S. Atomic Energy Commission, March 1974.

4.2 "Guide to the Safe Design Construction and Use of Radioisotopic Power Generators for Certain Land and Sea Applications," Safety Series No. 33, International Atomic Energy Agency, 1970.

4.3 "Guidelines for Applications for Registration of Sealed Sources," March 1982, obtained by personal communication, W. J. Pike (NUS) to E. G. Wright (USNRC, Office of Nuclear Material Safety and Safeguards), September 1, 1982.

4.4 "Guidelines for Applications, for Registration of Devices," March 1982, obtained by personal communication, W. J. Pike (NUS) to E. G. Wright (USNRC, Office of Nuclear Material Safety and Safeguards), September 1, 1982.

4.5 Personal Communication, W. J. Pike (NUS) to E. Wright and B. Singer (USNRC, Office of Nuclear Material Safety and Safeguards), August 30 and September 1, 1982.

5.1 "Review of NRC Licensing Requirements and Their Impact on the Development and Testing of the Kr-85 Runway Light," J. E. Slider and F. M. Quinn, NUS-3666, September 1980.

5.2 "Compilation of State Laws and Regulations on Transportation of Radioactive Materials," NUREG/CR-1263, Federal-State Reports, Inc. for the U. S. Nuclear Regulatory Commission, January 1980.

5.3 "Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material," Regulatory Guide 10.7, Revision 1, U. S. Nuclear Regulatory Commission, August 1979.

5.4 "Classification of Containment Properties of Sealed Radioactive Sources," Regulatory Guide 6.4, Revision 2, U. S. Nuclear Regulatory Commission, August 1980.

5.5 "Classification of Radioactive Self-Luminous Light Sources," American National Standard N540, American National Standards Institute Subcommittee N43-2, approved February 1975, issued January 1976.

5.6 "Sealed Radioactive Sources, Classification," American National Standard N542, American National Standards Institute Subcommittee N43-3.3, approved November 1977, issued July 1978.

6.1 Personal Communication, W. J. Pike (NUS) to R. A. Benedict (USNRC, Office of Nuclear Reactor Regulation), August 24 and September 13, 1982.

6.2 Personal Communication, W. J. Pike (NUS) to R. L. Ferguson (USNRC, Office of Nuclear Reactor Regulation), September 13, 1982.

6.3 Letter, R. L. Fergusion (DOE) to R. P. Denise (NRC), dated August 20, 1976.

6.4 Letter, R. L. Ferguson (DOE) to R. P. Denise (NRC), dated July 14, 1977.

APPENDICES A THROUGH E

March 1974

U.S. ATOMIC ENERGY COMMISSION

# REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

## REGULATORY GUIDE 6.3

## DESIGN, CONSTRUCTION, AND USE OF RADIOISOTOPIC POWER GENERATORS FOR CERTAIN LAND AND SEA APPLICATIONS

### A. INTRODUCTION

Manufacture or use of a radioisotopic power generator containing byproduct, source, or special nuclear material is an activity requiring a license pursuant to §30.3, "Activities Requiring License," of 10 CFR Part 30, §40.3, "License Requirements," of 10, CFR Part 40, or § 70.3. "License Requirements," of 10 CFR Part 70. This regulatory guide presents guidelines acceptable to the Regulatory staff for the safe design, construction, and use of radioisotopic power generators (other than those capable of being carried on or used at close proximity to the person) intended for use at defined locations on land and on or under the sea. In addition, guidance is provided for the preparation of a safety assessment report to be submitted as part of the information required by §30.32 for applications concerning byproduct material, by §40.31 for applications concerning source material, or by §70.22 for applications concerning special nuclear material to demonstrate that the applicant's proposed program is adequate to protect health and minimize danger to life or property.

### B. DISCUSSION

The increase in the development and production of certain types of radioisotopic power generators and their proposed use in international waters created a need for the formulation of internationally acceptable recommendations governing the health and safety aspects of their construction and use. Accordingly, the International Atomic Energy Agency and the European Nuclear Energy Agency jointly established a Working Group to study the health and safety problems associated with such devices. In 1970, that Working Group produced the document, "Guide to the Safe Design, Construction and Use of Radioisotopic Power Generators for certain Land and Sea Applications," which was published as IAEA Safety Series No. 33.[1] Safety Series No. 33 sets forth basic safety goals for the design, construction, and use of generators and, in Appendix III, provides suggested format and contents of a safety assessment report to be used to demonstrate that these safety goals have been met.

### C. REGULATORY POSITION

1. The guidelines set forth in IAEA Safety Series No. 33[1] for the safe design, construction, and use of radioisotopic power generators (other than those capable of being carried on or used at close proximity to the person) intended for use at defined locations on land and on or under the sea are generally acceptable, as supplemented by the following:

a. The requirements of 10 CFR Parts 20 and 71 with respect to basic safety standards and the transport of radioactive material should be followed in lieu of IAEA Safety Series No. 9 and No. 6.

b. In addition to the precautions stated in Section 2.3.3, "General Physical Security," periodic determinations of fuel capsule integrity should be performed. Site specific factors such as temperature and accessibility should be taken into account in selecting test frequency and method.

c. In addition to the provisions in Section 2.3.4, "Radiological Protection," records of installation, test, repair, and maintenance activities should be maintained.

d. In lieu of the reference to ISO standards in Section 2.8, "Exterior Marking," the outer surface marking should include the radiation symbol prescribed by §20.203(a) of 10 CFR Part 20.

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[1] Copies may be obtained from the IAEA Sales Agent (UNIPUB, Inc., P.O. Box 433, New York, New York 10016).

e. In lieu of the thermal test prescribed in Section 2.3 of Appendix I, the capsule should be heated in air to a temperature of 800°C or to its maximum operating temperature (whichever is higher) and that temperature should be maintained for a period of 30 minutes before being allowed to cool.

f. In lieu of the limit prescribed in Section 2.6 of Appendix I, the sensitivity of the leakage detection should be $10^{-8}$ (STP) $cm^3$/sec.

2. The suggested format and contents of a Safety Assessment Report set forth in Appendix III of IAEA Safety Series No. 33 are generally acceptable for demonstrating that the applicant's proposed program is adequate to protect health and minimize danger to life or property, as supplemented by the following:

a. In addition to the radioactive fuel properties listed in Section 2.2.1 of Appendix III, the report should include the maximum amount of fuel in grams and curies and pertinent data on radioisotopic impurities.

b. In addition to designating the person or organization to be responsible for certain activities in accordance with Section 2.8.1 of Appendix III, the report should describe pertinent radiation protection training and other experience of individuals assigned those responsibilities.

c. A request for the treatment of any information provided in the safety assessment report as proprietary should be submitted in accordance with the provisions of 10 CFR 2.790.

March 1982

APPENDIX B

# GUIDELINES FOR APPLICATIONS FOR REGISTRATION OF SEALED SOURCES

This guide has been prepared to assist manufacturers/distributors in the preparation of applications for registration of the design for sealed sources containing radioactive material. The objectives are:

- To identify and explain the elements of an application that are necessary to demonstrate the adequacy of the sealed source design from the standpoint of health and safety.
- To facilitate the consistent, effective and timely review of applications by the U.S. Nuclear Regulatory Commission (NRC) and Agreement States.
- To facilitate the preparation by reviewing agencies, NRC or Agreement States, of registration sheets in a prescribed format.

Applications for registration of sealed sources should contain the following three sections:

- A. Summary Data
- B. Descriptive Data
- C. Health and Safety Data

Guidelines for these three sections are presented below and are followed by Section D -- Specifications and Style.

## A. SUMMARY DATA

This section can normally be presented on one page and should contain key summary data as follows:

1. Date: Give the date of submission.

2. Sealed Source Type: Insert the short name commonly used by the manufacturer/distributor to identify the source.

3. Model: Insert the model number(s) or series number(s) used by the vendor to identify the sealed source.

4. Applicant: Give the name and complete mailing address of the organization submitting the application and indicate whether it is the manufacturer or distributor or both. Also give the name, title and telephone number of the person to be contacted for further information.

5. Other Companies Involved: Give the name and address of any other companies directly involved in the manufacture or distribution of this sealed source. For example, if the applicant distributes a device manufactured by the XYZ Company list the XYZ Company, Mfr., and give the mailing address.

6. Isotope and Maximum Activity: List the isotope(s) approved for use in a sealed source and the maximum acceptable activity level in terms of curies or millicuries for each approved isotope. If depleted uranium is used for shielding, show the number of grams of depleted uranium used.

7. Leak Test Frequency: State the recommended frequency for testing the sealed source for possible leakage of radioactive material. (More detailed testing information will be presented in Section C.)

8. Principal Use: Select from the attached list of principal uses (Exhibit 1) the term which most accurately describes the principal or predominant use intended for the sealed source or device.

9. Custom Source: Indicate by a "Yes" or "No" whether the sealed source is a custom source. If the answer is "Yes", present the basis for this determination. Sealed sources specifically designed and constructed according to the personal order of a single specific license applicant may be considered "CUSTOM" sealed sources for the purpose of a review tailored

to the single applicant. Sealed sources designed and constructed as off-the-shelf items or for use by more than a single license applicant shall not be deemed applicable to custom reviews and shall not be considered for a custom review and registration.

10. Custom User: If this is a custom source, give the name and address of the custom user.

B. DESCRIPTIVE DATA

This section should include the following:

1. Summary Description: Provide a precise, yet concise, description of the sealed source, including information on the chemical and physical form of the radioactivity, the materials used in the capsule construction, capsule dimensions and the methods for fabrication and sealing of the capsules. State the American National Standards Institutes (ANSI) classification designation of the source. Do not include information which has been determined to be "proprietary data." (See Exhibit 2, "Proprietary Data," for definition and guidance on the handling of proprietary data.)

2. Labeling: Describe the information to be engraved, etched or imprinted on a sealed source and the type of location of warning labels. The label for a sealed source should include the words: "CAUTION - RADIOACTIVE MATERIAL," manufacturer's name or trademark, model number or unqiue serial number, radionuclide, activity, assay date, and the radiation symbol. Where labeling the source is impracticable, a tag containing the above information should be attached to the source, unless the attachment of such a tag is also impracticable. When a sealed source is permanently mounted in a device, source labeling is not required, provided the device is labeled as specified above.

3. Diagram: Insert a small drawing of the sealed source showing the materials of construction, dimensions, method of sealing, and relationships of major components. Do not include information which has been determined to be "proprietary data." The diagram should be no larger than 4" by 6" and should be suitable for reproduction for use in a registration sheet.

4. Conditions of Normal Use: Describe the planned use of the sealed source and identify the environment and operating conditions expected during normal use. Include descriptions of the types of users, location of use, possibilities of use as a component in other products, and circumstances of normal use. Indicate the expected useful life of the source. Describe also the probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

5. Supporting Detail: Provide additional descriptive information which may be helpful in conveying to the reviewer a clear understanding of the sealed source and its detailed characteristics. This should include a design package containing engineering drawings of the sealed source, identifying all methods of construction, dimensions, methods of fabrication and method of sealing the source capsule(s).

If the information presented in the application contains data which the applicant considers to be proprietary data, such data should be clearly marked so that it can be handled appropriately. In addition, the letter transmitting the application should call attention to the inclusion of proprietary data. See Exhibit 2, "Proprietary Data," for definition and guidance on the handling of proprietary data.

Provide references to other pertinent documents, including previous applications and registration sheets.

C. HEALTH AND SAFETY DATA

This section should include the following:

1. Safety Analysis Summary: Provide a paragraph which summarizes the important facts pertaining to safety and the results of the safety analysis performed by the manufacturer/distributor. Include references to the appropriate ANSI, NBS or NRC standards used in the safety analysis.

2. Manufacturing and Distribution Controls: Describe the manufacturing and distribution controls applicable to the sealed source, giving attention to the following:

a. Quality Assurance and Control: Describe the quality control procedures to be followed in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications.

Describe the assay method used to determine the radioactive content of the sealed source. This method shall be traceable to a national standard.

Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled, "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcuries.

b. Description of Manufacturer's Recommended Maintenance, Servicing, and Testing Requirements for Use: Describe the manufacturer's recommendation for leak testing, unpacking, handling and disposal of the sealed source and specify availability of these services.

The normal leak test interval is six months. In the event the manufacturer, assembler, or distributor requests that a sealed source, upon transfer to the user, be considered for a leak test interval

greater than six months, sufficient information shall be submitted to demonstrate that such a longer interval is justified as a result of operating experience with identically sealed sources or similarly designed and constructed sealed sources used in similar conditions.

c. Manufacturer's Instructions to Users: Manufacturers or distributors of sealed sources distributed under these registration procedures should provide users with a copy of pertinent radiological safety and operating instructions for the source.

3. Manufacturer's Safety Analysis of Sealed Source Review: Each application for a sealed source review shall include a section which contains the manufacturer's Safety Analysis Report. This report shall contain, but not be limited to, the following information.

a. Safety Analysis: The analysis should determine the ability of the final design to withstand the normal condition of handling, use, and storage including such factors as abrasion, corrosion, vibration, impact, puncture, and the probable effects on containment of abnormal conditions such as fire or explosion.

b. Prototype Testing and Evaluation: Submit the following information:

- Maximum radiation levels at 5 and 30 centimeters from any external surface of the source averaged over an area not to exceed 100 square centimeters, and the method of measurement or calculation.
- Results of tests performed on prototype sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the source is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and, as a minimum, shall meet the designated usage classification according to the current ANSI standard entitled "Sealed Radioactive Sources, Classification," provided the means for assigning such a classification is described.

c. Additional Information: Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the sealed source.

## D. SPECIFICATIONS AND STYLE

Review, handling and filing of applications can be facilitated by observance of the following guidelines on specifications and style.

### 1. Physical Specifications

All pages in an application should be numbered consecutively. Text pages should preferably be printed on two sides with the image printed head to head.

If revisions are necessary subsequent to submission of an application, revised pages should be submitted. Each revised page should be numbered and show the date of revision. The revised portion of the page should be marked by a bold verticle line in the margin opposite the binding margin. If supplemental pages are submitted as part of the revision they may be numbered 13a, 13b, etc.

The preferred paper size is 8½ x 11 inches. If a larger size is used, the sheet, after reduction, should not exceed 11 x 17 inches, including a 2-inch margin at the left for binding. The finished copy when folded should not exceed 8½ x 11 inches.

A margin of no less than one inch should be maintained on the top, bottom and binding side of each sheet.

All drawings should have a drawing number, revision number, company name, title, date, and sheet number.

Type of paper, color of paper and ink, type font and style, and printing or reproduction method should be suitable for microfilming.

## 2. Style and Composition

The applicant should strive for clear, concise presentation of the information provided in the application. Confusing or ambiguous statements and unnecessarily verbose descriptions do not contribute to expeditious technical review. Claims of adequacy of designs or design methods should be supported by technical bases, i.e., by an appropriate engineering evaluation or description of actual tests. Terms as defined in the NRC regulations and American National Standards guides must be used.

Appendices may be used to include detailed information omitted from the main text for clarity. Examples of such information are summaries of the manner in which the applicant has treated matters addressed in NRC regulatory guides, supplementary information regarding calculational methods or design approaches used by the applicant or its agents, and lists of references mentioned in the text.

All physical tests of sealed source and devices should be supported by photographs in the appendices.

Where numerical values are stated, the number of significant figures given should reflect the accuracy or precision to which the number is known. Where possible, estimated limits of error or uncertainty should be given. Significant figures should not be dropped or rounded off if, by doing so, subsequent conclusions are inadequately supported.

Abbreviations should be consistent throughout the application and should be consistent with generally accepted usage. Any abbreviations, symbols, or special terms unique to the proposed sealed source or device not in general usage should be defined in each section of the application where they are used.

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Revised

# STANDARD LIST
# PRINCIPAL USES OF SEALED SOURCES AND DEVICES

| CODE | |
|---|---|
| A | Industrial Radiography |
| B | Medical Radiography |
| C | Medical Teletherapy |
| D | Gamma Gauges |
| E | Beta Gauges |
| F | Oil Well Logging |
| G | Portable Moisture Density Gauges |
| H | General Neutron Source Applications |
| I | Calibration Sources (Activity greater than 30mCi) |
| J | Gamma Irradiator, Category I |
| K | Gamma Irradiator, Category II |
| L | Gamma Irradiator, Category III |
| M | Gamma Irradiator, Category IV |
| N | Ion Generators, Chromatography |
| O | Ion Generators, Static Eliminators |
| P | Ion Generators, Smoke Detectors |
| Q | Thermal Generator |
| R | Gas Sources |
| S | Foil Sources |
| T | Other |
| U | X-Ray Fluorescence |
| V | General Medical Use |

EXHIBIT 1

DEFINITIONS FOR STANDARD LIST

PRINCIPAL USES OF SEALED SOURCES AND DEVICES

CODE

A — Industrial Radiography -- The examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive material.

B — Medical Radiography -- The process of producing x-ray or gamma-ray images to assist in the determination of medical diagnoses.

C — Medical Teletherapy -- The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient.

D — Gamma Gauges -- The use of gamma radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.

E — Beta Gauges -- The use of beta radiation to measure or control thicknesss, density levels, interface location, radiation leakage, or chemical composition.

F — Oil Well Logging -- The lowering and raising of measuring devices or tools which may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well and/or adjacent formations.

G — Portable Moisture Density Gauges -- Portable gauges which use a radioactive sealed source to determine/measure moisture content or density of material. This includes hand-held or dolly-transported devices/sources.

H — General Neutron Source Applications -- All applications, excluding reactor start-up, which use a neutron source.

I — Calibration Sources (Activity greater than 30mCi) -- Sources of a known purity and activity which are used to determine the variation in accuracy of a measuring instrument and to ascertain necessary correction factors.

CODE

| | |
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| J | Gamma Irradiator, Category I -- An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its design configuration. |
| K | Gamma Irradiator, Category II -- All applications which are panoramic and use dry source storage for irradiation of biologic or other materials. |
| L | Gamma Irradiator, Category III -- Applications which are self contained and use a wet source storage for irradiation of biologic and other materials. |
| M | Gamma Irradiator, Category IV -- Applications which are panoramic and use a wet source storage for irradiation of biologic and other materials. |
| N | Ion Generators, Chromatography -- Process of using an ion generating source to determine the chemical composition of material. |
| O | Ion Generators, Static Eliminators -- Process of using ion generating sources to eliminate static electricity on a surface or a surrounding area. |
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| S | Foil Sources -- Sources which are constructed using thin metal foil. The radioactive material may be secured to the foil in a number of ways, for example: plating, laminating, or cold welding. |
| T | Other -- All other uses or applications not covered in other categories. |

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| U | X-Ray Fluorescence -- Sources and/or devices utilizing radioactive material which excites the atoms of samples which, in turn, emit characteristic x-rays and thereby provide a means for sample analysis. |
| V | General Medical Use -- This category includes diagnostic sources and devices such as bone mineral analyzers and therapeutic sources and devices such as interstitial needles, therapeutic seeds, and opthalmic applicators. |

EXHIBIT 1 (continued)

## PROPRIETARY INFORMATION

A. Proprietary Information includes:

1. Trade secrets.

2. Privileged or confidential research, development, commercial or financial information exempt from mandatory disclosure under 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings," Sections 2.740 and 2.790 and under 10 CFR Part 9, "Public Records," Section 9.5, "Exemptions."

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C. Marking of Documents

1. On Origination or Submission Documents which contain trade secrets or other privileged or confidential commercial or financial information as set forth above, shall be marked to indicate that fact. Markings shall be placed on the document on origination. Documents claimed to be proprietary shall be so marked subject to an NRC determination that they contain proprietary information.

2. The words "PROPRIETARY INFORMATION" shall be placed conspicuously at the top and bottom of each page containing claimed proprietary information.

The wording set forth below shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

"TRADE SECRET OR PRIVILEGED OR CONFIDENTIAL COMMERCIAL OR FINANCIAL INFORMATION"

This document contains information submitted to the NRC by

_____
(Name of Company) (Name of Submitter)

which is claimed to be proprietary in accordance with (10 CFR 2.790(b)) (10 CFR 9.5) (10 CFR Part 21) and is exempt from mandatory public disclosure to 10 CFR Part 9.

WITHHOLD FROM PUBLIC DISCLOSURE

_____
(Signature and Title) (Office) (Date)

3. The NRC requests, whenever possible, that all information submitted under the claim of "Proprietary Information" be extracted from the main body of the application and submitted as a separate annex or appendix to the application. This procedure will facilitate the processing of the application.

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# GUIDELINES FOR APPLICATIONS FOR REGISTRATION OF DEVICES

This guide has been prepared to assist manufacturers/distributors in the preparation of applications for registration of the design for devices containing radioactive material. The objectives are:

- To identify and explain the elements of an application that are necessary to demonstrate the adequacy of the device design from the standpoint of health and safety.
- To facilitate the consistent, effective and timely review of applications by the U.S. Nuclear Regulatory Commission (NRC) and Agreement States.
- To facilitate the preparation by reviewing agencies, NRC or Agreement States, of registration sheets in a prescribed format.

Applications for registration of sealed sources and devices should contain the following three sections:

- A. Summary Data
- B. Descriptive Data
- C. Health and Safety Data

Guidelines for these three sections are presented below and are followed by Section D -- Specifications and Style.

## A. SUMMARY DATA

This section can normally be presented on one page and should contain key summary data as follows:

1. Date: Give the date of submission.

2. Device Type: Insert the short name commonly used by the manufacturer/distributor to identify the device.

3. Model: Insert the model number(s) or series number(s) used by the vendor to identify the device.

4. Applicant: Given the name and complete mailing address of the organization submitting the application and indicate whether it is the manufacturer or distributor or both. Also give the name, title and telephone number of the person to be contacted for further information.

5. Other Companies Involved: Give the name and address of any other companies directly involved in the manufacture or distribution of this device. For example, if the applicant distributes a device manufactured by the XYZ Company list the XYZ Company, Mfr., and give the mailing address.

6. Sealed Source Model Designation: List the sealed sources, by vendor and model number, approved for use in the device.

7. Isotope and Maximum Activity: List the isotope(s) approved for use in the sealed source(s) which may be used in the device and the maximum acceptable activity level in terms of curies or millicuries for each approved isotope. If depleted uranium is used for shielding, show the number of grams of depleted uranium used.

8. Leak Test Frequency: State the recommended frequency for testing the device for possible leakage of radioactive material. (More detailed testing information will be presented in Section C.)

9. Principal Use: Select from the attached list of principal uses (Exhibit 1) the term which most accurately describes the principal or predominant use intended for the sealed source or device.

10. Custom Device: Indicate by a "Yes" or "No" whether the device is a custom device. If the answer is "Yes", present the basis for this determination. Devices specifically designed and constructed according to the

personal order of a single specific license applicant may be considered "CUSTOM" devices for the purpose of a review tailored to the single applicant. Devices designed and constructed as off-the-shelf items or for use by more than a single license applicant shall not be deemed applicable to custom reviews and shall not be considered for a custom review and registration.

11. Custom User: If this is a custom device, given the name and address of the custom user.

B. DESCRIPTIVE DATA

This section should include the following:

1. Summary Description: Provide a precise, yet concise, description of the device. Describe the essential factors pertaining to device design, including dimensions, materials of construction, methods of fabrication shielding, "on-off" mechanisms, "on-off" indicators and methods for securing the source in the device. State the American National Standards Institute (ANSI) classification designation of the device and the source(s) used in the device. Do not include information which has been determined to be "proprietary data." (See Exhibit 2, "Proprietary Data," for definition and guidance on the handling of proprietary data.)

2. Labeling: Describe the information to be engraved, etched or imprinted on a device and the type of location of warning labels. The label for a sealed source should meet the requirements of Section 20.203, 10 CFR Part 20.

The label or marking for a device should consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, and type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION-RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful life of

the device and be readily visible. For devices intended for distribution to persons generally licensed pursuant to 31.5 10 CRF Part 31, the label shall comply with the requirements of Section 32.51(a)(3), 10 CRF Part 32.

3. Diagram: Insert a small pictorial diagram or sketch showing critical components of the device, such as materials of construction, shielding thickness, "on-off" mechanism, "on-off" indicators, and approximate dimensions. Do not include information which has been determined to be "proprietary data." The diagram should be no larger than 4" by 6" and should be suitable for reproduction for use in a registration sheet.

4. Conditions of Normal Use: Describe the planned use of the device and identify the environment and operating conditions expected during normal use. Include descriptions of the types of users, locations of use, possibilities of use as a component in other products, and circumstances of normal use. Indicate the expected useful life of the source. Describe also the probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

5. Supporting Detail: Provide additional descriptive information which may be helpful in conveying to the reviewer a clear understanding of the device and its detailed characteristics.

Provide a design package including engineering drawings of the sealed source, source holder, source housing. These drawings should identify all material of construction, dimensions, methods of fabrication and methods for incorporating the sealed source and all critical safety components into the device. This package should also contain drawing and descriptions of a typical installation for the device.

If the information presented in the application contains data which the applicant considers to be proprietary data, such data should be clearly marked so that it can be handled appropriately. In addition, the letter transmitting the application should call attention to the inclusion of proprietary data. See Exhibit 2 "Proprietary Data," for definition and guidance on the handling of proprietary data.

Provide references to other pertinent documents, including previous applications and registration sheets.

C. HEALTH AND SAFETY DATA

This section should include the following:

1. Safety Analysis Summary: Provide a paragraph which summarizes the important facts pertaining to safety and the results of the safety analysis performed by the manufacturer/distributor. Include references to the appropriate ANSI, NBS or NRC standards used in the safety analysis.

2. Manufacturing and Distribution Controls: Describe the manufacturing and distribution controls applicable to the device, giving attention to the following:

a. Quality Assurance and Control: Describe the manufacturer's quality assurance and control program, using, for example, the approach set forth in Appendix B, ANSI N538 for devices.

Describe the quality control procedures to be followed in the fabrication and assembly of the device and the quality control standards for maintaining source design specifications. Also, if available, describe the quality assurance aspects and provide certificate(s) of compliance related to the device.

Describe the source manufacturer's assay method used to determine the radioactive content of the sealed source(s) used in the device. This method shall be traceable to a national standard.

Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled, "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcuries.

b. Description of Manufacturer's Recommended Maintenance, Servicing, and Testing Requirements for Use: Describe the device manufacturer's recommendations for: installation and relocation; initial radiation surveys; leak testing; repair, periodic maintenance and shutter checks; source exchange; emergency procedures and disposal. Also specify the availability of these services.

The normal leak test interval is six months. If a longer interval is proposed, the basis for the longer interval must be justified.

c. Manufacturer's Instructions to Users: Manufacturers or distributors of devices distributed under these registration procedures should provide users with a copy of pertinent radiological safety and operating instructions for the device.

Each distributor shall provide with each device:

- o A certification that the sealed source has been appropriately tested for leakage and contamination within six months of date of transfer.
- o A certificate of assay for each source.
- o Instructions for the safe usage of the source/device.

The normal leak test interval is six months. If a longer interview is proposed, the basis for the longer interval must be justified.

3. Manufacturer's Safety Analysis of Device Review: Each application for a device review shall include a section which contains the manufacturer's Safety Analysis Report. This report shall contain, but not be limited to, the following information.

a. Safety Analysis: The safety analysis should be based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use, and storage including abrasion, corrosion, vibration, impact, puncture, compressive loads, and the probable effects on containment and shielding of abnormally severe conditions, such as explosion and fire. Aging effects are of particular importance. The results of testing which demonstrate that

the device meets the designated performance classification according to the current ANSI Standard entitled, "Classification of Industrial Radiation Gauging Devices" shall also be submitted.

b. Prototype Testing and Evaluation: At least one device shall be evaluated. The prototype device tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe operation of the devices requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

The manufacturer, assembler, or distributor, shall submit information including:

- Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and, as a minimum, shall meet the designated usage classification according to the current ANSI standard entitled "Sealed Radioactive Sources, Classification."

- A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage including abrasion, corrosion, vibration, impact, puncture, compressive loads, and the probable effects on containment and shielding of abnormally severe conditions, such as explosion and fire. Aging effects are of particular importance. The results of testing which demonstrate that the device meets the designated performance classification according to the current ANSI standard entitled "Classification of Industrial Ionizing Radiation Gauging Devices" shall also be submitted.

- Radiation profiles (isodose curves, e.g., 2 and 5 mR/h) of a prototype of the devices with shutter(s) in the open and closed position(s). Radiation levels should be measured using the maximum activity of each kind of radioactive material expected to be used in the device. A description of the method used to measure the radiation levels should be included.

For devices intended for distribution to persons generally licensed pursuant to 31.5, 10 CFR Part 31, provide sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:
  - Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye.....0.5 rem
  - Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter.....7.5 rems
  - Other organs.....3.0 rems
- Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any individual would receive an external radiation dose or dose commitment in excess of the following organ doses:
  - Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye.....15 rems
  - Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter.....200 rems
  - Other organs..... 50 rems

c. Additional information: Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the sealed source and/or device.

## D. SPECIFICATIONS AND STYLE

Review, handling and filing of applications can be facilitated by observance of the following guidelines on specifications and style.

### 1. Physical Specifications

All pages in an application should be numbered consecutively. Text pages should preferably be printed on two sides with the image printed head to head.

If revisions are necessary subsequent to submission of an application, revised pages should be submitted. Each revised page should be numbered and show the date of revision. The revised portion of the page should be marked by a bold verticle line in the margin opposite the binding margin. If supplemental pages are submitted as part of the revision they may be numbered 13A, 13B, etc.

The preferred paper size is 8½ x 11 inches. If a larger size is used, the sheet, after reduction, should not exceed 11 x 17 inches, including a 2-inch margin at the left for binding. The finished copy when folded should not exceed 8½ x 11 inches.

A margin of no less than one inch should be maintained on the top, bottom and binding side of each sheet.

All drawings should have a drawing number, revision number, company name, title, date, and sheet number.

Type of paper, color of paper and ink, type font and style, and printing or reproduction method should be suitable for microfilming.

2. Style and Composition

The applicant should strive for clear, concise presentation of the information provided in the application. Confusing or ambiguous statements and unnecessarily verbose descriptions do not contribute to expeditious technical review. Claims of adequacy of designs or design methods should be supported by technical bases, i.e., by an appropriate engineering evaluation or description of actual tests. Terms as defined in the NRC regulations and American National Standards guides must be used.

Appendices may be used to include detailed information omitted from the main text for clarity. Examples of such information are summaries of the manner in which the applicant has treated matters addressed in NRC regulatory guides, supplementary information regarding calculational methods or design approaches used by the applicant or its agents, and lists of references mentioned in the text.

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which is claimed to be proprietary in accordance with (10 CFR 2.790(b)) (10 CFR 9.5) (10 CFR Part 21) and is exempt from mandatory public disclosure to 10 CFR Part 9.

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U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
August 1979

# REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT



## REGULATORY GUIDE 10.7

## GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES OF BYPRODUCT MATERIAL *

### 1. INTRODUCTION

This guide describes the type of information needed by the NRC staff to evaluate an application for a specific license for laboratories and industries using millicurie quantities of byproduct material (reactor-produced radionuclides). This type of license is provided for under Title 10, Code of Federal Regulations, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Paragraph 20.1(c) of 10 CFR Part 20, "Standards for Protection Against Radiation," states that "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable" (ALARA). Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. License applicants should give consideration to the ALARA philosophy, as described in Regulatory Guide 8.10, in the development of plans for work with licensed radioactive materials.

### 2. LICENSE FEES

An application fee is required for most types of licenses. The applicant should refer to §170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC.

### 3. FILING AN APPLICATION

An applicant for a byproduct material (radioisotopes) license should complete Form NRC-313I (see the appendix to this guide).[1] All items on the application form should be completed in sufficient detail for the NRC to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form NRC-313I is limited, the applicant should append additional sheets to provide complete information. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number (on Form NRC-313I) and its purpose (e.g., radiation safety instructions).

The application should be completed in triplicate. The original and one copy should be mailed to the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. One copy of the application, with all attachments, should be retained by the applicant since the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it.

*Lines indicate substantive changes from previous issue

[1] Applications for medical uses should be submitted on Form NRC-313M, and applications for use of sealed sources in radiography should be submitted on Form NRC-313R.

## 4. CONTENTS OF AN APPLICATION

Most items of Form NRC-313[1] are self-explanatory (see instructions with the form). The following comments apply to the indicated numbered items of the form.

Items 2 and 4. Specify the applicant corporation or other legal entity by name and address of principal office. Individuals should be designated as the applicant only if the use of the byproduct material is not connected with the individual's employment with a corporation or other entity. If the applicant is an individual, the individual should be specified by full name and address, including state and zip code.

Item 5. Specify the street address of the location of use if the address differs from the one given in Item 4. If use is to be at more than one location, the specific address of each should be given. Describe the extent of use and the facilities and equipment at each location. A post office box address is not acceptable.

Item 6. Specify the names of the persons who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 7. Specify the name of the person who will be designated as the radiation protection officer.[2] This person should be responsible for implementing the radiation safety program and therefore readily available to the users in case of difficulty and should be trained and experienced in radiation protection and in the use and handling of radioactive materials. In a small program not requiring a full-time radiation protection officer, the duties of the radiation protection officer may be assigned to one of the persons named under Item 6 of Form NRC-313I. Note, however, that it must be established that the person acting as radiation protection officer will have the opportunity to devote sufficient time to the radiation safety aspects of the program for the use of radioactive materials.

Items 8A, B, C, and D. Describe the byproduct material by isotope, chemical and/or physical form, and activity, in millicuries or microcuries. A separate possession limit for each nuclide should be specified. Possession limits requested should cover the total anticipated inventory, including stored materials and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

If the use of sealed or plated sources is contemplated, the isotope, manufacturer, and model number of each sealed or plated source should be specified. If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device should be specified.

Item 8E and Item 9. The use to be made of the radioactive materials should be clearly described. Sufficient detail should be given to allow a determination of the potential for exposure to radiation and radioactive materials both of those working with the materials and of the public.

Items 10 and 11. Specify for each radiation detection instrument the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detected (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness in $mg/cm^2$, and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring.

Describe the instrument calibration procedure. State the frequency, and describe the methods and procedures for the calibration of survey and monitoring instruments, as well as any other instruments and systems used in the radiation protection program, such as measuring instruments used to assay sealed-source leak-test samples (see Item 15), contamination samples (e.g., air samples, surface "wipe" samples), and bioassay samples (see Item 12).

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instruments should be supplemented every 6 months with a two-point calibration on each scale of each instrument with the two points separated by at least 50% of the scale. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. Readings within ±20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

If the applicant proposes to calibrate his survey instruments, a detailed description of planned calibration procedures should be submitted. The description of calibration procedures should include, as a minimum:

a. The manufacturer and model number of each radiation source to be used,

[2]The terms "radiation protection officer" and "radiological safety officer" are synonymous

b. The nuclide and quantity of radioactive material contained in each source,

c. The accuracy of the source(s). The traceability of the source to a primary standard should be provided.

d. The step-by-step procedures, including associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the calibrations.

If the applicant intends to contract out the calibration of instruments, the name, address, and license number of the firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Commission. If information concerning calibration procedures has not been filed, it should be obtained and submitted.

Quantitative measuring instruments used to monitor the adequacy of containment and contamination control such as those used for measuring leak test, air, effluent, bioassay, work area, and equipment contamination samples should usually be calibrated prior to each use. The procedures and frequency for calibration of such instruments should be submitted and should include:

a. The name of the manufacturer and model number of each of the standards to be used,

b. The nuclide and quantity of radioactive material contained in each of the standard sources,

c. A statement of the accuracy of each of the standard sources. The source accuracy should be, as a minimum, ±5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Bureau of Standards.

d. Step-by-step calibration procedures and, if appropriate, associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the instrument calibrations

Item 12. Personnel monitoring is required to ensure compliance with §§20.101 and 20.202 of 10 CFR Part 20. Personnel monitoring is also required if a person enters a high radiation area (greater than 100 millirems per hour). If personnel monitoring equipment will be used, the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service and the frequency for changing badges, dosimeters, etc., should be specified. If pocket chambers or pocket dosimeters will be used, the useful range of the device, in milliroentgens, the frequency of reading, and the procedures for maintaining and calibrating the devices should be specified.

If personnel monitoring will not be used, the applicant should submit calculations or documentation from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 10 CFR Part 20.

The applicant should show that the need for bioassays has been thoroughly considered and should establish the adequacy of the proposed bioassay program in relation to the proposed program of use of radioactive material. Bioassays are normally required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 depending on the type of work, equipment, and procedures followed. Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," and a document entitled "Guidelines for Bioassay Requirements for Tritium"[3] may be consulted. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be considered and discussed in relation to each such material, procedure, etc. Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," may be consulted.

The criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures should be specified and described in detail. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well-thought-out and well-executed handling procedures.

Item 13. The facilities and equipment for each site of use should be described in detail. The proposed facilities and equipment for each operation to be conducted should be adequate to protect health and minimize danger to life and property. In describing available facilities and equipment, the following should be included, as appropriate:

a. Physical plant, laboratory, or working area facilities. Fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, and

[3]A copy may be obtained by a written request to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Fuel Cycle and Material Safety, Washington, D.C. 20555, Attention: Director, Office of Nuclear Material Safety and Safeguards.

all processing, work, and protective clothing change areas should be described.

A drawing or sketch should be submitted showing the location of all such equipment and the relationship of areas where radioactive materials will be handled to unrestricted areas where radioactive materials will not be handled. In those programs where radioactive material may become airborne or may be included in airborne effluents, the drawing or sketch should also include a schematic description of the ventilation system annotated to show airflow rates, differential pressures, filtration and other effluent treatment equipment, and air and effluent monitoring instruments. Drawings or sketches should be drawn to a specified scale, or dimensions should be included on each drawing or sketch. Each drawing or sketch should be labeled to specify the location of the facilities and equipment depicted with respect to the address(es) given in Item 5 of Form NRC-313I.

b. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Special provisions for shielding and containment to minimize personnel exposure should be described. Storage containers and facilities should provide both shielding and security for materials.

c. The number, type, and length of remote handling devices.

d. If respiratory protective equipment will be used to limit the inhalation of airborne radioactive material, the provisions of §20.103 of 10 CFR Part 20 should be followed and appropriate information should be submitted.

Item 14. The procedures for disposing of byproduct material waste should be described. Under NRC regulations, a licensee may dispose of waste in the following ways:

a. Transfer to a person properly licensed to receive such waste in conformance with paragraph 20.301(a) of 10 CFR Part 20. The name of the firm (which should be contacted in advance to determine any limitations that the firm may have on acceptance of waste) should be given.

b. Release into a sanitary sewer in conformance with §20.303 of 10 CFR Part 20. Depending on water usage, releases of up to 1 curie per year are permitted.

c. Burial in soil in conformance with §20.304 of 10 CFR Part 20. Up to 12 burials per year are permissible. The allowable quantity depends upon the radionuclide.[4]

d. Release into air or water in concentrations in conformance with §20.106 of 10 CFR Part 20. Possible exposure to persons offsite limits the amount that may be released.

e. Treatment or disposal by incineration in conformance with §20.305 of 10 CFR Part 20. This must be specifically approved by the Commission.

f. Other methods specifically approved by the Commission pursuant to §20.302 of 10 CFR Part 20.

Item 15

a. Survey Program. Commission regulations require that surveys be made to determine if radiation hazards exist in a facility in which radioactive materials are used or stored (see §20.201 of 10 CFR Part 20). A survey should include the evaluation of external exposure to personnel, concentrations of airborne radioactive material in the facility, and radioactive effluents from the facility. Although a theoretical calculation is often used to demonstrate compliance with regulations regarding airborne or external radiation, it cannot always be used in lieu of a physical survey.

Except for those cases where sources of radiation and radioactive material are well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement instruments to determine the nature and extent of radiation and radioactive material or, as a minimum, confirm the results of a theoretical determination.

A radiation protection program should include the following surveys for radioactive contamination and radiation:

(1) In laboratory or plant areas (e.g., checking for contamination on bench tops, handling and storage equipment, clothing, hands).

(2) While work is being done with radiation or radioactive materials (e.g., breathing zone air surveys; general air surveys; personnel exposure measurements, including eyes and extremities; checking shutters and containment).

(3) In areas associated with disposal or release of radioactive materials (e.g., checking

[4]The NRC has proposed an amendment that would delete §20.304 of 10 CFR Part 20 (43 FR 56677, December 4, 1978). If this amendment is adopted, all burials of radionuclides in accordance with §20.304 of 10 CFR Part 20 will require NRC approval.

disposal containers and disposal sites; liquid, gas, and solid effluents, filters and filter-duct systems).

The frequency of surveys will depend on the nature of the radioactive materials and their use. However, surveys should be performed prior to the use of radioactive materials in order to establish a baseline. The surveys should be repeated when radioactive materials are present, when the quantity or type of material present changes, or when changes occur in their containment systems or methods of use. Repetitive surveys may also be necessary to control the location of radioactive materials in the handling system and in the case of the use of sealed sources outside a shielded container.

For operations involving materials in gas, liquid, or finely divided forms, the survey program should be designed to monitor the adequacy of containment and control of the materials involved. The program should include air sampling, monitoring of effluents, and surveys to evaluate contamination of personnel, facilities, and equipment. Physical effluent measurements are essential to determine compliance with Appendix B to 10 CFR Part 20.

The description of an air sampling program should include the area where samples will be taken, the frequency of sampling, and the location of the sampler with respect to workers' breathing zones. Assays performed to evaluate air samples and the methods used to relate results to actual personnel exposures should also be described.

The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid radioactive material releases. Theoretical evaluations should be supplemented by stack monitoring, water sampling, and other environmental monitoring appropriate for the planned and potential releases

For operations involving only sealed sources, a survey program should include evaluation and/or measurement of radiation levels for storage and use configurations. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be performed following any changes in operation, shielding, or use.

The types, methods, and frequency of surveys should be described in the application. Guidance may be obtained from the National Council on Radiation Protection Report No. 10, "Radiological Monitoring Methods and Instruments,"[5] and the International Atomic Energy Agency's Technical Report Series No 120, "Monitoring of Radioactive Contamination on Surfaces."[6]

b. Records Management Program. Provision for keeping and reviewing records of surveys; materials inventories; personnel exposures; receipt, use, and disposal of materials, etc., should be described. Persons responsible for keeping and reviewing records should be identified.

c. Sealed-Source Leak-Test Procedures. Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha emitter must be leak tested at 6-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at 3-month intervals. If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit," the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information should be submitted:

(1) Qualifications of personnel who will perform the leak test,

(2) Procedures and materials to be used in taking test samples,

(3) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples,

(4) Instrument calibration procedures, including calibration source characteristics, make, and model number, and

(5) The method, including a sample calculation, to be used to convert instrument readings to units of activity, e.g., microcuries.

d. Instructions to Personnel. If a number of individuals will use radioactive materials under the supervision of one or more of those persons named in Item 6 of Form NRC-313I, written instructions should be prepared and submitted with the license application in the form in which they will be distributed to those working with radioactive materials. These instructions should cover, but not necessarily be limited to:

(1) The availability, selection, and use of laboratory apparel and safety-related equipment and devices (e.g., laboratory coats, gloves, and remote pipetting devices).

[5]Copies may be obtained from NCRP Publications, P.O. Box 4867, Washington, D.C. 20008.

[6]Copies may be obtained from UNIPUB Inc., P.O. Box 433, New York, N.Y. 10016.

(2) Limitations and conditions to be met in handling liquid or uncontained (unencapsulated, dispersible, or volatile) radioactive materials and special laboratory equipment to be used in working with these types of materials. For example, the instructions should explain when operations with materials should be confined to a radiochemical fume hood or glove box and should specify the use of appropriate shielding and remote handling equipment when energetic beta- or gamma-emitting materials are to be used.

(3) The performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.

(4) Safety precautions to be observed in the movement of radioactive materials between buildings, rooms, and areas within rooms.

(5) Safety requirements for storage of radioactive materials, including labeling of containers of radioactive materials and posting and securing areas where radioactive materials are to be stored. This should include the storage of contaminated laboratory equipment such as glassware.

(6) Requirements for posting of areas in which radioactive materials are used.

(7) The availability and use of personnel monitoring devices, including the recording of radiation exposures and the procedures to be followed for the processing of personnel monitoring devices such as thermoluminescent dosimeters and film badges in order to obtain personnel monitoring results.

(8) Waste disposal procedures to be followed, including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage, and disposal of other wastes.

(9) The maintenance of appropriate records as required by 10 CFR Part 20 and 10 CFR Part 30.

(10) The requirements for and the method of performing or having appropriate sealed-source leak tests performed.

(11) Good radiation safety practices, including the control of contamination, specification of acceptable removable and fixed contamination levels for both restricted and unrestricted areas, prohibition of smoking and the consumption of food or beverages in areas where radioactive materials may be used, and prohibition of the frequent transfer of potentially contaminated equipment between potentially contaminated areas and unrestricted areas.

(12) The use of radioactive materials in animals. If radioactive materials will be used in animals, instructions concerning such use should be prepared and submitted with the license application. Such instructions should include (a) specification of the facilities to be used to house the animals, (b) instructions to be provided to animal caretakers for handling animals, animal wastes, and carcasses, (c) instructions to appropriate personnel for cleaning and decontaminating animal cages, and (d) methods to be used to ensure that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive materials. A description of animal handling and housing facilities should be included under Item 13 of Form NRC-313I.

(13) Emergency procedures. These instructions should be addressed to all persons in all laboratory or facility areas where radioactive materials will be used and should cover actions to be taken in case of such accidents involving radioactive materials as spills, fires, release or loss of material, or accidental contamination of personnel. Specifically, these instructions should (a) specify immediate actions to be taken in order to prevent or limit the contamination of personnel and areas, e.g., the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas, containment of any spills of radioactive material, (b) give the telephone numbers of individuals to be notified in case of emergency, and (c) instruct personnel in proper entry, decontamination, and recovery operations for contaminated facilities. (Note: Only properly trained individuals should attempt decontamination and recovery operations.)

(14) Requirements and procedures for picking up, receiving, and opening packages (see §20.205 of 10 CFR Part 20).

Items 16 and 17. A resumé of the training and experience of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibilities for radiological safety should be submitted. The resumé should include the type (on-the-job or formal course work), location, and duration of the training. Training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of radioactive materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. The qualifications, training, and

experience of each person should be commensurate with the material and its use as proposed in the application. The amount and type of training and experience with radiation and radioactive materials required to support a determination of adequacy by the Commission will vary markedly with certain factors.

If other persons such as technical assistants and laboratory workers will use radioactive materials in the absence of persons specified above, the specification of the training of such personnel should include (a) instruction in radiation safety including topics covered and by whom taught, (b) on-the-job training in use of radioactive materials, and (c) determination of competency to work without the presence of supervisory personnel.

The use of microcurie quantities of a few nonvolatile radioactive materials by a person with a minimum of training and experience under precisely specified and carefully controlled conditions subject to the surveillance of a competent and adequately trained radiation protection officer may be justified. Such minimum training and experience may consist of a few hours of training and experience in the use of one or more radioactive materials similar to the use proposed in the application under the supervision and tutorship of a licensed user.

Persons using millicurie quantities of a number of radionuclides for general laboratory tracer work under unspecified conditions should have more extensive training and experience and, depending on the exact nature of the proposed program of use of radionuclides, may need to have completed formal course work at the college or university level covering the areas listed under Item 16 of Form NRC-313I.

The use of larger quantities of material (approaching a curie) under conditions where a potential exists for significant loss and ingestion, inhalation, or absorption of the radioactive material by those working with the material is normally done under carefully controlled conditions using specialized equipment. A person who is to use radioactive materials independently under these conditions should not only have a background of formal training in all areas described in Item 16 of Form NRC-313I but should also have extensive experience working with radioactive material and a thorough working knowledge of the equipment required to handle the material safely.

## 5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supportive documents. The license must therefore be amended if the licensee plans to make any changes in facilities, equipment (including monitoring and survey instruments), procedures, personnel, or byproduct material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

## 6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313I, appropriately supplemented, and should contain complete and up-to-date information about the applicant's current program.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page, and paragraph.

# APPENDIX A

Form NRC-313 (I)
(1/79)
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

Form Approved by GAO
B-180225(RO579)

## INSTRUCTIONS FOR PREPARATION OF APPLICATION FOR BYPRODUCT MATERIAL LICENSE

## FORM NRC-313 (I)

### GENERAL INFORMATION

An applicant for a "Byproduct Material (Radioisotopes) License," should complete Form NRC-313 (I) in detail and submit in duplicate to the U.S. Nuclear Regulatory Commission. The applicant should endeavor to cover his entire radioistope program with one application, if possible. However, separate applications should be submitted for gamma irradiators. Applications for medical uses should be submitted on Form NRC-313 (M) and applications for use of sealed sources in radiography should be submitted on Form NRC-313R. Supplemental sheets may be appened when necessary to provide complete information. *Item 18 must be completed on all applications. Submission of an incomplete application will often result in a delay in issuance of the license because of the correspondence necessary to obtain information requested on the application.*

NOTE. -When the application includes one of the special uses listed below, the applicant should request the appropriate pamphlet which provides additional instructions.

1 Industrial Radiography "Licensing Requirements for Industrial Radiography" (use application Form NRC-313R for Radiography);

2 Laboratory and Industrial Uses of Small Quantities-"Guide for Preparation of Applications for Laboratory and Industrial Uses of Small Quantities of Byproduct Material."

3. Broad License (research and development)-"Licensing Guide for Type-A Licenses of Broad Scope for Research and Development,"

4. Licensing Guides for the performance of well logging operations.

5. Licensing guide for the use of sealed sources in portable and semi-portable gauging devices.

The Commission charges fees for filing of applications for licenses as specified in Section 170.12, Title 10 Code of Federal Regulations, Part 170. The applicant should refer to Section 170.31, *Schedule of fees for materials licenses*, to determine what fee should accompany the application. No action can be taken on applications until fees are paid. Checks or money orders should be made payable to the U.S. Nuclear Regulatory Commission.

Two copies of the completed Form NRC-313 (I) and two copies of each attachment thereto should be sent to the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. One copy should be retained for the applicant's file. Applications may also be filed in person at the Commission's office at 1717 H Street, N.W., Washington, D.C. or at 7915 Eastern Avenue, Silver Spring, Maryland.

### EXPLANATION OF FORM NRC-313 (I)

Form NRC-313 (I) is designed for use in supplying information on programs of varying complexity. The applicant should provide complete information on his proposed program for the possession and use of licensed material. For those items that do not apply, indicate as N.A. (not applicable).

Item No.

1. Self-explanatory

2. The "applicant" is the organization or persons legally responsible for possession and use of the licensed materials specified in the application.

3. Self-explanatory

4. Self-explanatory

5. The actual sites of use should be listed as indicated. Permanent facilities such as field offices for portable gauges or devices should be identified in Item 5 by Street, Address, City and State. Temporary field locations of use should be specified as "temporary job sites of the applicant" and list the States throughout which the temporary job sites will be located. Attach additional properly keyed sheet if more space is needed.

6. Self-explanatory

7. The "Radiation Protection Officer" is the named individual who is expected to coordinate the safe use of the licensed material specified in the application and who will ensure compliance with the applicable parts of Title 10, Code of Federal Regulations.

8. List by name each radioisotope to be possessed and used under the license. Example:

| A | B | C | D |
|---|---|---|---|
| (1) Iodine-131 | (1) Iodide | (1) Not Applicable | (1) 10 millicuries |
| (2) Iodine-131 | (2) Iodinated Human Serum Albumin | (2) N. A. | (2) 1 millicurie |
| (3) Krypton-85 | (3) Gas | (3) N. A. | (3) 1 millicurie |
| (4) Cesium-137 | (4) Sealed Source | (4) Iso. Corp Model Z-78 | (4) 2 source of 150 millicuries each |

Attach additional properly keyed sheets if more space is needed.

8.E State the use of each licensed material listed in 8.A, B, C, and D.

9. Description of containers and/or devices in which sealed sources listed in Item 8 will be stored or used. Example:

| A | B | C |
|---|---|---|
| (1) #4 - Source housing | Iso. Corp | Model Z-278 |

10 18 Self-explanatory (For those items that do not apply, indicate as N.A. (not applicable).

## PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Forms NRC-313M, NRC-313a, NRC-313I or NRC-313R. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. AUTHORITY: Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. PRINCIPAL PURPOSE(S): The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a byproduct material license or amendment thereof.

3. ROUTINE USES: The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident of exposure for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N. W., Washington, D.C.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION: Disclosure of the requested information is voluntary. If the request information is not furnished, however, the application for byproduct material license, or amendment thereof, will not be processed.

5. SYSTEM MANAGER(S) AND ADDRESS: Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

FORM NRC-313 I (1-79)
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

# APPLICATION FOR BYPRODUCT MATERIAL LICENSE
## INDUSTRIAL

*See attached instructions for details.*

*Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.*

**1. APPLICATION FOR:** *(Check and/or complete as appropriate)*

- ☐ a. NEW LICENSE
- ☐ b. AMENDMENT TO: LICENSE NUMBER
- ☐ c. RENEWAL OF: LICENSE NUMBER

**2. APPLICANT'S NAME** *(Institution, firm, person, etc.)*

TELEPHONE NUMBER AREA CODE – NUMBER EXTENSION

**3. NAME OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION**

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION

**4. APPLICANT'S MAILING ADDRESS** *(Include Zip Code)*

**5 STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED** *(Include Zip Code)*

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

**6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL**
*(See Items 16 and 17 for required training and experience of each individual named below)*

| | FULL NAME | TITLE |
|---|---|---|
| a. | | |
| b. | | |
| c. | | |

**7. RADIATION PROTECTION OFFICER**

*Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.*

**8. LICENSED MATERIAL**

| LINE NO. | ELEMENT AND MASS NUMBER A | CHEMICAL AND/OR PHYSICAL FORM B | NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)* C | MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D |
|---|---|---|---|---|
| (1) | | | | |
| (2) | | | | |
| (3) | | | | |
| (4) | | | | |

| | DESCRIBE USE OF LICENSED MATERIAL E |
|---|---|
| (1) | |
| (2) | |
| (3) | |
| (4) | |

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## 9. STORAGE OF SEALED SOURCES

| LINE NO. | CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A. | NAME OF MANUFACTURER B. | MODEL NUMBER C. |
|---|---|---|---|
| (1) | | | |
| (2) | | | |
| (3) | | | |
| (4) | | | |

## 10. RADIATION DETECTION INSTRUMENTS

| LINE NO. | TYPE OF INSTRUMENT A | MANUFACTURER'S NAME B | MODEL NUMBER C | NUMBER AVAILABLE D | RADIATION DETECTED (alpha, beta, gamma, neutron) E | SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F |
|---|---|---|---|---|---|---|
| (1) | | | | | | |
| (2) | | | | | | |
| (3) | | | | | | |
| (4) | | | | | | |

## 11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

☐ b. CALIBRATED BY APPLICANT

*Attach a separate sheet describing method, frequency and standards used for calibrating instruments.*

## 12. PERSONNEL MONITORING DEVICES

| TYPE (Check and/or complete as appropriate.) A | SUPPLIER (Service Company) B | EXCHANGE FREQUENCY C |
|---|---|---|
| ☐ (1) FILM BADGE | | ☐ MONTHLY |
| ☐ (2) THERMOLUMINESCENCE DOSIMETER (TLD) | | ☐ QUARTERLY |
| ☐ (3) OTHER (Specify): _____ | | ☐ OTHER (Specify): |
| _____ | | _____ |
| _____ | | _____ |

## 13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☐ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC

☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC

☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.

☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

## 14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

## INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where appliçable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

## 18. CERTIFICATE

*(This item must be completed by applicant)*

*The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.*

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

| | |
|---|---|
| a LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)* | b. CERTIFYING OFFICIAL *(Signature)* |
| | c. NAME *(Type or print)* |
| (1) LICENSE FEE CATEGORY: | d. TITLE |
| (2) LICENSE FEE ENCLOSED: $ | e. DATE |

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APPENDIX E

Revision 2
August 1980

U.S. NUCLEAR REGULATORY COMMISSION

# REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT



REGULATORY GUIDE 6.4

## CLASSIFICATION OF CONTAINMENT PROPERTIES OF SEALED RADIOACTIVE SOURCES

### A. INTRODUCTION

Section 32.51, "Byproduct Material Contained in Devices for Use under § 31.5; Requirements for License to Manufacture or Initially Transfer," of 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," requires, in part, that each application for a specific license to distribute devices containing byproduct material to persons generally licensed under § 31.5 of 10 CFR Part 31 include sufficient information relating to qualification testing of a prototype unit to provide reasonable assurance that the byproduct material in the device will be adequately contained.

Section 32.74, "Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use," of 10 CFR Part 32 requires, in part, that applications for licenses to distribute sources and devices for use in medical programs under § 35.14 include information on procedures for prototype tests and the results of such tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents. Also, vendors to other materials licensees are required to submit similar qualification testing information when requesting approvals for standardized source or device designs. Retention of radioactive material within a device or source is dependent on the containment properties of the source.

This regulatory guide identifies terminology acceptable to the NRC staff for describing the containment properties of a source on a prototype testing basis.

### B. DISCUSSION

The USA Standards Institute (USASI) Committee N5.4, now the American National Standards Institute Committee N43-3.3, developed a classification system for sealed sources, USASI N5.10-1968. This standard was later revised and issued as ANSI N542-1977, "Sealed Radioactive Sources, Classification,"[1] (also identified as NBS Handbook 126[2]).

Subsequent to development of the sealed source classification system contained in USASI N5.10-1968, the American National Standards Institute Committee N43-2 developed a related classification system for radioactive self-luminous light sources, ANSI N540-1975, "Classification of Self-Luminous Light Sources,"[1] (also identified as NBS Handbook 116[2]). This latter system concerns a specialized group of sources that use radiation from radioactive material to activate phosphors and produce light.

To classify a source under either system, the system in ANSI N540-1975 or the system in ANSI N542-1977, a determination is made of the ability of the source to withstand the conditions of each environmental test prescribed in the respective standard. Classification is determined by physically testing two prototype sources for each test or by calculations based on previous tests which demonstrate that, if the source were tested, it would pass. With one exception, maintenance of containment integrity after each test constitutes satisfactory performance of a source. The exception is the ANSI N540-1975 discoloration test. Satisfactory performance for this test is determined by appropriate retention of luminosity during the test.

### C. REGULATORY POSITION

The sealed source classification systems contained in ANSI N540-1975 and ANSI N542-1977 provide acceptable terminology for use in describing the containment properties of a sealed source used in a device or a self-luminous light source intended for distribution for use

*Lines indicate substantive changes from Revision 1.

[1]Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

[2]Copies may be purchased at current rates from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

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under the general license in § 31.5 of 10 CFR Part 31 or under a specific license. When either classification system is so used, the applicant should state whether calculational techniques or physical testing techniques were applied. If the physical testing techniques were applied, the integrity (leak) test(s) used to determine conformity with the assigned classification made in accordance with the provisions of ANSI N542-1977 should be identified and described.

## D. IMPLEMENTATION

The guidance contained herein may be used upon issuance of this revision by any person submitting an application for a specific license pursuant to Sections 32.51 and 32.74 of 10 CFR Part 32 and vendors requesting approvals for standardized source or device designs. Other effective means of providing information relating to qualification testing of a prototype unit also may be used.