DRAFT SUPPORTING STATEMENT FOR 10 CFR PART 30
"RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL"
(3150-0017)

CLEARANCE EXTENSION

Description of Information Collection

The Nuclear Regulatory Commission's regulations in 10 CFR Part 30 establish rules applicable to all persons in the United States governing domestic licensing of radioactive byproduct material. The regulations were issued pursuant to the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, as amended, and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. Among the provisions of the licenses issued by the Nuclear Regulatory Commission are conditions which impose requirements on the licensee, including reporting and recordkeeping. These include frequently used established standard license conditions and less frequently used new technology/uses standard license conditions.

Some of the conditions imposed are specific to the particular licensee as dictated by that licensee's particular facilities, equipment, or type of use of material. Other conditions are applied more generally--some to all licensees, and some to certain types of licensees based on the category of use of radioactive material (e.g., radiography, medical human use, etc.). Those are known as "established standard license conditions." Established standard license conditions are utilized by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Title 10 of the Code of Federal Regulations (10 CFR) that the licensee commits to when applying for a license. Those standard license conditions which contain reporting or recordkeeping requirements are described in detail in Section 30.34(e)(4). This ongoing burden has not been previously captured in the supporting statement for 10 CFR Part 30. Therefore, this burden is submitted as an addition to the previous 10 CFR Part 30 submittal.

The new technology/uses standard license conditions are imposed on individual licensees and groups of licensees engaged in new materials uses or the use of new technologies in established materials uses. New technology/uses standard license conditions will be utilized by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Title 10 of the Code of Federal Regulations (10 CFR) that the licensee commits to when applying for a license. Those new technology/uses standard license conditions which contain reporting or recordkeeping requirements similar to those in the regulations and established license conditions are described in Section 30.34(e)(4). This ongoing burden has not been previously captured in the supporting statement for 10 CFR Part 30. Therefore, this burden is submitted as an addition to the previous 10 CFR Part 30 submittal.

A. Justification

1. Need for and Practical Utility of the Collection of Information

Section 30.9(b) requires that an applicant or licensee notify the Commission of information which the applicant or licensee recognizes as having significant implications for public health and safety or the common defense and security. This requirement applies only to information which is not already required to be provided to the Commission by other reporting or updating requirements. The information must be provided within 2 working days to the administrator of the appropriate NRC regional office.

This requirement is necessary because there may be some circumstances in which a licensee possesses some information which could be important to the protection of public health and safety or the common defense and security, but which is not otherwise required to be reported. The codification of this full disclosure requirement should not result in significant additional burdens on applicants or licensees. No formal program is required. It is expected that licensees will maintain a professional attitude toward safety and that, if some potential safety information is identified by the licensee, the information will be provided freely and promptly to the NRC so that the agency can evaluate it and act on it, if necessary.

Section 30.11 provides that the Commission may, upon the application of any interested person or on its own initiative, grant exemptions from the requirements of 10 CFR Parts 30-36 and 39 under specified conditions.

The information submitted under this section is examined by the NRC to determine whether the requested exemption is authorized by law, and will not endanger life or property or the common defense and security, and is otherwise in the public interest.

Section 30.15(b) requires that any person who desires to apply byproduct material to, or to incorporate it into, the products exempted in Section 30.15(a), or who desires to initially transfer for sale or distribution such products containing byproduct material, apply for a specific license pursuant to Section 32.14. Such a license indicates that the product may be distributed by the licensee to persons exempt from the regulations (hereinafter "exempt persons").

The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review of the information and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, “Application for Material License,” is used to collect this information and is cleared under OMB Clearance No. 3150-0120.

Section 30.18(d) indicates that no person may, for purposes of commercial distribution, transfer byproduct material in the quantities set forth in Section 30.71, Schedule B, to exempt persons, except in accordance with a license issued under Section 32.18.

The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review and the findings therefore form the basis for NRC licensing decisions. NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.19(b) requires that any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products to exempt persons for use, apply for a license pursuant to Section 32.22, with a license provision that the product may be transferred to exempt persons.

The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.20(b) requires that any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products to exempt persons for use, apply for a license pursuant to Section 32.26, with a license provision that the product may be initially transferred to exempt persons.

The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.32(a) requires that applications for specific licenses for byproduct material be submitted on NRC Form 313, "Application for Material License." The NRC reviews the information submitted on the NRC Form 313 to determine whether an applicant for a license has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety.

NRC Form 313 is cleared under OMB Clearance No. 3150-0120.

Section 30.32(b) provides that NRC may require further statements after the filing of the application, and before the expiration of the license, to enable NRC to determine whether the application should be granted or denied or whether a license should be modified or revoked. Such additional information is sometimes needed to clarify information submitted in the application, or to rectify deficiencies in proposed or existing programs for protection of the public health and safety, the common defense and security, or the environment.

The additional information is reviewed by various NRC organizational units to assess the adequacy of the applicant's physical plant, procedures, and plans for protection of the public health and safety, common defense and security, and the environment. The NRC review and the findings therefrom form the basis for

NRC decisions concerning the issuance, modification, or revocation of licenses for byproduct material.

The burden and cost associated with further statements is included in the burden and cost data for submittal of applications on NRC Form 313, which is cleared under OMB Clearance No. 3150-0120.

Section 30.32(f) requires that an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment must be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental report required pursuant to 10 CFR Part 51, Subpart A.

Facilities for commercial waste disposal, or other activities covered by this section, are generally large and complex and have the potential to significantly affect the quality of the human environment. NRC's consideration of environmental effects and balancing of alternatives for the project, as mandated by the "National Environmental Policy Act of 1969," requires the applicant to submit a comprehensive and detailed environmental report. The NRC licensing staff reviews the environmental report to assure that it is complete and that it considers and balances alternatives for the project in order to best protect the environment.

This section refers to and requires the submission of information pursuant to 10 CFR Part 51. The collection of information, the burden imposed on respondents, and the cost to the Government are contained in the supporting statement for 10 CFR Part 51, which is cleared under OMB Clearance No. 3150-0021.

Section 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number, as registered with the NRC under Section 32.210 or with an Agreement State, or contain the radiation safety related information that is identified in Section 32.210(c). This information is needed by the NRC to determine the adequacy of the radiation safety properties of the source and device under the conditions of proposed use. This determination is used to establish that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property.

The burden and cost data associated with these registrations are included in the supporting statement for 10 CFR Part 32, which is cleared under OMB Clearance No. 3150-0001.

Section 30.32(i) requires applicants that will possess amounts of materials requiring an emergency plan to either submit an evaluation demonstrating an emergency plan is not needed or to provide the emergency plan. Those requiring an emergency plan must also commit to providing prompt notification to offsite response organizations and NRC in the event of an event triggering the emergency plan. The evaluation or emergency plans are submitted in the new license application, amendment, or renewal process. NRC Form 313,

“Application for Material License,” is used to collect this information and is cleared under OMB Clearance No. 3150-0120.

The records and reports required in Section 30.32(i) are necessary for the Commission to determine whether the applicant will be able to respond adequately to an accident and to provide the proper notifications to NRC and off site response organizations to adequately protect the public health and safety in the event of an accident.

Section 30.34(b) requires that the licensee provide full information before transferring, assigning, or in any manner disposing of any license through transfer of control to any person. No action is required of a licensee unless and until a transfer of control is initiated.

The information required by Section 30.34(b) is used only to verify that the licensing information that was previously submitted on Form 313, “Application for Material License,” is still correct, and to permit the NRC to determine whether the proposed licensee provides adequate resources to protect public health and safety. The NRC review of the information and the findings therefore form the basis for NRC licensing decisions.

Section 30.34(e)(4) permits the Commission to incorporate in any license issued pursuant to the regulations in 10 CFR Parts 30-36 and 39 additional requirements and conditions with respect to the licensee’s receipt, possession, use, and transfer of byproduct material. In addition, reports and the keeping of records may be required, as necessary, to fulfill the purposes of the Atomic Energy Act and regulations of the Commission.

Established Standard License Conditions:

Established standard license conditions are developed based on the licensee's particular facilities, equipment, or type of use of material or based on the category of use of radioactive material (e.g., radiography, medical human use, etc.). These conditions are used by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. The established standard license conditions which contain reporting or recordkeeping requirements are described in detail below.

Conditions 22 and 23 Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years after the individual’s last use of licensed material. Licensed material shall be used by or under the supervision of individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual’s last use of licensed material.

Condition 164 The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of

each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Condition 165(i) requires that the licensee maintain records of leak test results in units of microcuries for 5 years.

The new technology/uses standard license conditions:

These conditions are imposed on individual licensees and groups of licensees engaged in new materials uses or the use of new technologies in established materials uses. These conditions are developed to account for the unique properties of the new uses or new technologies and used to ensure the same degree of public health and safety is applied uniformly for similar established and developing materials uses. In most cases, the new technology/uses standard recordkeeping conditions are used to modify the specific information required in recordkeeping requirements for a similar established use. These are also used to document alternative procedures needed to meet the objective of a procedure specifically included in the regulations or established standard license conditions (such as leak test that cannot be performed as described in either the regulations or the established standard leak test license condition). In a few cases, the recordkeeping requirement will be needed to assure unique safety significant information is retained. The new technology/uses standard license conditions may also be used to ensure reporting of events involving the new materials uses and new technologies that are substantially the same as existing reportable events contained in the regulations but are not technically described in the regulation (e.g., reporting an error in the medical use of an emerging medical technology when the unique characteristics of the technology are not specifically addressed in the medical event reporting regulation).

This regulation is also cited as the authority, when necessary, for the issuance of orders for the modification of licenses. When the issuance of such orders involves the imposition of reporting or recordkeeping requirements, requests for OMB clearance of the specific information collection requirements are submitted, as necessary.

The information is used by the NRC staff to verify that the licensee has performed required actions in a complete and timely manner.

Section 30.34(g) requires each licensee preparing technetium-99m radio-pharmaceuticals from molybdenum-99/technetium-99m generators to test the generator eluates for molybdenum-99 breakthrough in accordance with Section 35.204. The licensee is required to record the results of each test and maintain records of the test results for 3 years.

The requirement to maintain the records of test results is necessary to permit the NRC inspection staff to determine that nuclear pharmacy licensees and broad medical licensees have conducted the tests to determine the amount of molybdenum-99 in technetium-99 radioactive drugs before administration to patients. If excessive molybdenum-99 is present, it would result in unnecessary radiation doses to patients.

Section 30.34(h) requires that a licensee immediately notify the appropriate NRC regional administrator, in writing, following the filing of a bankruptcy petition by or against the licensee or a controlling or affiliate entity. No action is required of a licensee unless and until a petition for bankruptcy is filed.

This information is needed because a licensee who is experiencing severe economic hardship may not be capable of carrying out licensed activities in a manner that protects public health and safety. In particular, a licensee involved in bankruptcy proceedings can have problems affecting payment for proper handling of licensed radioactive material and for decontamination and decommissioning of the licensed facility in a safe manner. Improper materials handling or decontamination activities can lead to spread of contamination throughout a licensee's facility and the potential for dispersion of contaminated material offsite. Financial difficulties can also result in problems affecting the licensee's waste disposal activities.

The information provided by the notification is used by the NRC regional inspection and licensing staff, in consultation with headquarters legal and program staff, to determine the need for prompt NRC response or regulatory action in the event of a potential hazard to public health and safety posed by a licensee that does not have the resources to properly secure the licensed material or clean up possible contamination. In addition, prompt notification would allow the Commission to take timely and appropriate action in a bankruptcy proceeding to seek to have available assets of the licensee applied to cover costs of cleanup before funds are disbursed and become unavailable for cleanup.

Section 30.35 sets forth the requirements for financial assurance and recordkeeping for decommissioning. Sections 30.35(a) and (b) specify which licensees are required to submit a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided. Sections 30.35(c) and (d) specify the criteria for and required amounts of financial assurance for decommissioning. Section 30.35(e) specifies the content of the decommissioning funding plan. Section 30.35(f) specifies acceptable methods for providing for financial assurance for decommissioning: either through prepayment; a surety method, insurance or other guarantee method; or, in the case of Government licensees, a statement of intent containing a cost estimate for decommissioning.

Section 30.35(g) requires that each person licensed under 10 CFR Parts 30, 32-36, and 39 keep records of information important to the safe and effective decommissioning of the facility until the license is terminated by the Commission. Licensees are required to list in a single document (to be held by the licensee and updated once every 2 years) identification of all restricted areas where licensed materials were used or stored, all areas outside of restricted areas where documentation is required for unusual occurrences or spills, and all areas outside of restricted areas where waste has been buried or which contain material such that, if the license expired, the licensee would be required to either decontaminate the area or seek special approval for disposal. This information is needed by the NRC to ensure that no future users of the site will be inadvertently exposed to radiation.

The records and reports required by Section 30.35 are necessary for the Commission to determine whether an applicant will be able to carry out the requirements of Section 30.36 which specify that licensed premises must be decontaminated to a level "suitable for release for unrestricted use" before the license may be terminated. NRC will review the information to ensure that adequate funds will be available to ensure that the applicant will conduct decontamination efforts in a timely manner and minimize exposure of workers to radioactive materials. The information will also be used to ensure that the decontamination efforts will reduce the residual radioactive contamination sufficiently to protect the public health and safety after the site is released for unrestricted use.

Section 30.36 specifies procedures for terminating licensee responsibility for nuclear materials and clarifies that a license will continue in effect, with respect to possession of byproduct material, until the Commission notifies the licensee in writing that the license is terminated. Section 30.36(d) requires each licensee to notify the Commission in writing of its decision not to renew its license and to either begin decommissioning its site or submit within 12 months of notification a decommissioning plan. Section 30.36(e) requires that coincident with the notification required by Section 30.36(d), licensees maintain all decommissioning financial assurances established by the licensee pursuant to Section 30.35. Section 30.36(e)(2) was formerly Section 30.36(b)(2)(ii) which allows licensees that have an approved decommissioning funding plan to semiannually request a reduction in the amount of their required financial assurance as decommissioning proceeds and radiological contamination is reduced at the site. The reference for this section was change in July 1995 as a result of a Final Rule on Clarification of Decommissioning Funding Requirements. Section 30.36(g) requires that a decommissioning plan be submitted, if required by license condition or if the proposed procedures and activities necessary to carry out the decommissioning have not been previously approved by the Commission, and these procedures could increase potential health and safety impacts to workers or to the public.

Section 30.36(h) requires licensees in certain circumstances to request license termination (a license amendment process whose burden and cost is included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120).

All of the above information required by Section 30.36 is reviewed by the NRC to determine that there is no significant risk to public health and safety before a licensee's responsibility for nuclear materials is terminated and a facility is released for unrestricted use.

Section 30.36(j) requires, as a final step in decommissioning, that a licensee certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314, "Certificate of Disposition of Materials." In addition, this section requires that the licensee conduct a radiation survey of the site where the licensed activities were carried out and note on NRC Form 314 whether or not the survey was conducted and, if so, attach the results, if not separately forwarded to NRC. The radiation survey, similar to those generated during operations, is required to confirm the absence of radioactive materials or to establish the level of residual radioactive contamination. The information on

disposal of nuclear materials and the survey are considered the minimum information necessary to establish a record to support a finding that a license can be safely terminated. NRC Form 314 is cleared under OMB Clearance No. 3150-0028.

Section 30.37(a) requires that an application for renewal of a specific license be filed in accordance with Section 30.32. The NRC reviews the information submitted to determine whether an applicant for a license renewal has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety.

The burden and cost data for these applications for renewal of specific licenses have been included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120.

Section 30.38 requires that an application for amendment of a license be filed in accordance with Section 30.32. The NRC reviews the information submitted to determine whether the licensee has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety.

The burden and cost data for these applications for license amendments have been included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120.

Sections 30.41(c) and (d). Section 30.41(c) requires that, before transferring byproduct material to a specific licensee or a general licensee who is required to register prior to receipt of byproduct material, the transferor must verify that the transferee's license authorizes receipt of the type, form, and quantity of byproduct material to be transferred. Section 30.41(d) specifies methods acceptable to the Commission for accomplishing the required verification, including:

(1) The transferor may have in his possession, and read, a copy of the transferee's specific license or registration certificate.

(2) The transferor may have a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification from the transferee, provided it is confirmed in writing within 10 days.

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or Agreement State licensing agency.

(5) When the above methods of verification are not available, the transferor may obtain and record confirmation from the Commission or Agreement State licensing agency.

The information required by Sections 30.41(c) and (d) is used by transferring

licensees to provide assurance that the licensed byproduct material is being transferred to a person who is authorized to receive it. This verification serves as an additional check to prevent transfer of byproduct material to persons who may not have the facilities, training, experience, equipment, or procedures necessary for the safe handling of the material. Records of these certifications will be reviewed by NRC inspectors during periodic inspections to ensure that licensees have been complying with verification requirements.

Section 30.50 requires licensees to notify NRC of events or conditions that threaten the health and safety of individuals either using or potentially exposed to licensed material. Section 30.50(a) requires licensees to notify the NRC as soon as possible, but no later than 4 hours, of events that prevent immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed the regulatory limits. Section 30.50(b) requires licensees to notify the NRC within 24 hours after the discovery of any of the following events involving licensed material. Licensees must report unplanned contamination events, such as those in which access to an area must be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area. It is important that the NRC be notified in such cases because accidental contamination events increase radiation exposure and the risk of ingesting radioactive material.

Licensees are required to report events in which equipment necessary to prevent uncontrolled releases of radioactive material, to prevent overexposure to radiation, or to mitigate the consequences of an accident is disabled or fails to function as designed. This includes procedural errors, equipment failure, equipment damage, etc. This notification is necessary in situations in which there are no backup systems available to perform the required safety function. Notification is not required for an individual component failure if redundant systems are operable and available to automatically perform the required function. Licensees are required to report events that require medical treatment of a radioactively contaminated individual at a medical facility. Such events are significant because they may: (1) indicate safety problems in a licensed operation, (2) risk internal contamination through open wounds, and (3) expose medical personnel to radiation and contamination. Prompt notification is necessary so that NRC can ensure that an evaluation is performed and that measures are taken to prevent recurrence. Licensees are also required to report all fires and explosions damaging any licensed material or any device, container, or equipment containing licensed material, so that such events may be promptly evaluated and measures taken to minimize any spread of contamination and determine the performance of features designed to control licensed material.

Licensees are required to make the reports required by Sections 30.50(a) and (b) by telephone to the NRC Operations Center. In addition to the telephone report, licensees must submit a written follow-up report within 30 days which includes, in addition to descriptive information, an evaluation of the probable cause, a description of corrective actions taken or planned, and the results of any evaluations or assessments.

Section 30.51 establishes overall record retention requirements applicable to byproduct material licensees for cases in which retention periods are not otherwise specified in the regulations.

Section 30.51(a) requires that each licensee who receives byproduct material must keep records showing the receipt, transfer, and disposal of the byproduct material. It provides for retention of records of receipt of byproduct material as long as the material is possessed and for 3 years following transfer or disposal of the material, provides a 3-year retention period for records of transfer of byproduct material, and provides that records of disposal of licensed material must be maintained until the Commission terminates the license that authorizes the disposal.

Section 30.51(b) requires that records which are required by the regulations in 10 CFR Parts 30-36 and 39 or by license conditions must be maintained for the period specified by the appropriate regulation or license condition. In any case in which a retention period is not specified, the records must be maintained until the Commission terminates the license that authorizes the subject activity.

Sections 30.51(d) and (f) requires that the licensee transfer disposal records, survey records and other records important to decommissioning to the NRC prior to license termination.

Records are necessary as a primary source for determination that licensees have confined their possession and use of byproduct material to the locations and purposes authorized in the licenses and have not violated or failed to observe any of the terms and provisions of the Atomic Energy Act or any regulation or order of the Commission. Records of receipt can demonstrate that the licensee has received byproduct material of the element and mass number and in the chemical and/or physical form specified in the license. Records of transfer can demonstrate that the licensee has transferred byproduct material of the type, form, and quantity that transferees are authorized to receive. Records of disposal can demonstrate that the licensee has obtained approval of disposal procedures and/or has disposed of byproduct material in accordance with NRC regulations. Records of receipt, transfer, and disposal, taken together, can demonstrate that the licensee has possessed at any one time no more than the maximum quantity of byproduct material authorized in the license. The retention periods provide reasonable assurance that records will be available for Commission inspection after the recorded event.

Section 30.55(c) requires that each person who is authorized to possess tritium shall report promptly to the appropriate NRC regional office any incident in which any attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or 100 curies of such material in any one calendar year. The initial report shall be followed within 15 days by a written report which contains the details of the incident, its consequences, and any substantive additional information.

The information submitted by licensees under this requirement is used by the regional office to determine whether there has been a diversion or other loss of material and to initiate prompt action in the event of such diversion or loss. The written reports submitted to NRC regional offices are duplicate copies of reports filed with the Federal Bureau of Investigation on the theft or unlawful diversion of tritium.

Appendix A establishes criteria for parent companies to pass the financial test and to obtain a parent company financial guarantee. It specifies various financial ratios, including net worth and asset/liability ratios, and bond ratings. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. If the parent company no longer meets the financial test requirements, the licensee must send notice to NRC of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent within 90 days after the end of the fiscal year for which year-end financial data show that the company no longer meets the financial test requirements. The notice is necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site.

Appendix C establishes criteria for companies to pass the financial test and to obtain a self guarantee for financial assurance. It specifies various financial ratios, including net worth ratios, and bond ratings. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. If the company no longer meets the financial test requirements, the licensee must send immediate notice to NRC of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. The notice is necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site.

Appendix D establishes criteria for companies with no outstanding rated bonds to pass the financial test when they furnish their own guarantee that funds will be available for decommissioning cost. It specifies net tangible worth, assets, ratios of cash flow and ratios of these to the total current decommissioning cost estimates. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. If the company no longer meets the financial test requirements, the licensee must send immediate notice to NRC of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. The notice is necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site.

Appendix E establishes criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own guarantee that funds will be available to cover the decommissioning cost. It specifies bonds, unrestricted endowment, total revenue ratios, current assets, operating revenues and various other financial ratios. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. If the company no longer meets the financial test requirements, the licensee must send immediate notice to NRC

of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. The notice is necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site.

2. Agency Use of the Information

The records that 10 CFR Part 30 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material.

The records of receipt, transfer, and disposal of byproduct material are reviewed by the NRC inspectors to determine that licensees have confined their possession and use of byproduct material to the locations, purposes, receipt, and quantities authorized in their licenses.

Reports of significant safety events and theft of radioactive material are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could exceed regulatory limits and, therefore, impact public health and safety, the common defense and security, and the environment.

Bankruptcy reports, decommissioning plans, decommissioning funding plans, and certifications of financial assurance for decommissioning are reviewed by the NRC to ensure that a licensee has adequate procedures and funds for any necessary clean-up efforts before a licensee's responsibility for byproduct materials is terminated and the site is released for unrestricted use.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages applicants and licensees to use new automated information technology when it would be beneficial to them. However, the applications and reports do not lend themselves readily to the use of automated information technology for submission because of the varied types of information and the infrequency of submission. Consequently, the current percentage of electronic submissions is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. In general, information required by NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. The collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

There is no similar information available to the NRC that can be used to evaluate

compliance with NRC requirements governing the domestic licensing of byproduct material; to ensure public health and safety from NRC-licensed activities; and to identify trends and events that must be corrected to ensure continued safe practices.

5. Effort to Reduce Small Business Burden

The majority of licensees who use byproduct material are small businesses. Since the health and safety consequences of improper handling or use of radioactive byproduct material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the possession, use, or transfer of byproduct material.

The required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for renewal of licenses are usually submitted every 10 years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.6(b), Section 30.9(b) requires that licensees submit a notification to NRC in less than 30 days from the date of identifying information having significant implications for the public health and safety or the common defense and security and which is not covered by other reporting requirements. The requirement to provide notification within 2 working days following the identification of the information is necessary to ensure that NRC is made aware of the significant safety information so as to take prompt action to protect the public health and safety.

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.5(d)(2),

a. Condition 164 requires that records of inventories be maintained for 5 years from the date of each inventory so that they will be available for review during inspections for materials accountability.

b. Condition 165(i) requires that licensees maintain records of leak tests results for 5 years so that they will be available for review during inspections to demonstrate compliance with NRC radiation safety requirements.

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 30.34(h) requires that licensees submit a notification to NRC in less than 30 days from the date of filing of a petition for bankruptcy. The requirement to provide notification promptly following the filing of the petition is necessary to ensure that NRC is made aware of the bankruptcy so as to take effective action to protect the public health and safety. Allowing a period of 30 or more days to elapse might preclude NRC from becoming aware of the licensee's distressed financial circumstances in time to prevent the development or aggravation of a potential hazard to the public. Moreover, the United States Code contains requirements regarding notification of creditors in bankruptcy. Section 30.34(h) would require one additional notification. Notifying NRC promptly after the filing of the petition would in fact be less of a burden on the bankrupt licensee than a separate notification later in the proceedings.

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Section 30.35(g) requires that licensees keep records important to the safe and effective decommissioning of the facility until the license is terminated by the Commission. It is necessary that the records be retained longer than 3 years so that the Commission may determine whether an applicant will be able to carry out the requirements of Section 30.36 which specify that licensed premises must be decontaminated to a level "suitable for release for unrestricted use" before the license may be terminated. NRC reviews the information to ensure that adequate funds will be available to ensure that the applicant will conduct decontamination efforts in a timely manner and minimize exposure of workers to radioactive materials. The information is also used to ensure that the decontamination efforts will reduce the residual radioactive contamination sufficiently to protect the public health and safety after the site is released for unrestricted use.

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 30.36 requires each licensee who does not apply for license renewal to notify the Commission immediately in writing of its decision not to renew its license and to request termination of the license. This notification in less than 30 days is necessary to permit the NRC staff to determine whether any prompt measures may be needed to ensure that radioactive material is safely transferred or disposed of, and that there is no significant risk to public health and safety before a licensee's responsibility for nuclear materials is terminated and a facility is released for unrestricted use.

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 30.50 requires licensees to notify NRC immediately (i.e., within 4 hours) by telephone of events or conditions that threaten the health and safety of individuals using licensed material or that prevent the performance of surveys or other safety-related duties necessary to maintain control over licensed material. It is important that the NRC be notified in such cases because accidental contamination events increase radiation exposure and the risk of ingesting radioactive material. Immediate notification is needed so that such events may be promptly evaluated and measures taken to minimize any spread of contamination and determine the performance of features designed to control licensed material.

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Section 30.51(a) requires retention of records of receipt of byproduct material as long as the material is possessed and for 3 years following transfer or disposal, provides a 3-year

retention period for records of transfer of byproduct material, and provides that records of disposal of licensed material must be maintained until the Commission terminates the license. Section 30.51(b) requires that records which are required by the regulations in 10 CFR Parts 30-36 and 39, or by license conditions, must be maintained for the period specified by the appropriate regulation or license condition. In any case in which a retention period is not specified, the records must be maintained until the Commission authorizes their disposition.

These records are necessary as a primary source for determination that licensees have confined their possession and use of byproduct material to the locations and purposes authorized in the licenses and have not violated or failed to observe any of the terms and provisions of the Atomic Energy Act or any regulation or order of the Commission. Records of receipt can demonstrate that the licensee has received byproduct material of the element and mass number and in the chemical and/or physical form specified in the license. Records of transfer can demonstrate that the licensee has transferred byproduct material of the type, form, and quantity that transferees are authorized to receive. Records of disposal can demonstrate that the licensee has obtained approval of disposal procedures and/or has disposed of byproduct material in accordance with NRC regulations. Records of receipt, transfer, and disposal, taken together, can demonstrate that the licensee has possessed at any one time, no more than the maximum quantity of byproduct material authorized in the license. Retention for longer than 3 years, where required, is necessary to provide reasonable assurance that records will be available for Commission inspection after the recorded event.

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 30.55(c) requires that each person who is authorized to possess tritium shall report promptly to the appropriate NRC regional office, by telephone and telegraph, mailgram, or facsimile, any incident in which any attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or 100 curies of such material in any one calendar year. The initial report must be followed within 15 days by a written report setting forth the details of the incident and its consequences. Receipt of these reports in less than 30 days is necessary to permit the regional office to determine whether there has been a diversion or other loss of material and to initiate prompt action in the event of such diversion or loss. The written reports submitted to NRC regional offices which set forth the details of the incident, its consequences, and any substantive additional information are duplicate copies of reports filed with the Federal Bureau of Investigation on the theft or unlawful diversion of tritium.

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Appendix C requires licensees to notify NRC immediately, (i.e., within 4 hours) if the company no longer meets the financial test requirements, of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. It is important that the NRC be notified immediately in such cases to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.

8. Consultations Outside the NRC

The opportunity for public comment has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Reports submitted are generally subject to public disclosure in accordance with 10 CFR 2.790 and 10 CFR Part 9. Section 2.790 allows the NRC to withhold certain proprietary information (information of commercial value or "trade secrets") if, at the time of submittal of the report, the requirements for withholding the information are met (refer to 10 CFR 2.790(b)). Also, there are provisions in 10 CFR Part 9 for the NRC to withhold some documents, such as reports of radiation exposure to individuals and other personal records, from public disclosure.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

The estimates are based on submittals to NRC in past years. The cost to licensees and applicants is calculated at a rate of $152 per hour for professional staff for the technical reports and records prepared in response to the 10 CFR Part 30 information collection requirements. This rate is based on NRC's fully recoverable fee rate. The recordkeeping requirements in Sections 30.41(c) and (d), and 30.51 are calculated at a rate of $63 per hour, because these requirements can be fulfilled using automated equipment, computer-generated reports and administrative/clerical staff. These figures include both salaries and overhead.

NRC Licensees:

The total annual burden is estimated to be about 44,413 hours per year for the 4,678 licensees covered by 10 CFR Part 30. The details are shown in Tables 1 and 2.

Cost for NRC licensees @ $63/hour = $1,104,831 [17,537 hours (17,117 recordkeeping hours for Sections 30.41(c)&(d) and 30.51+ 420 reporting hours for Sections 30.51(d)&(f)]

Cost for NRC licensees @ $152/hour = $4,085,152 [26,876 hours (7,496 recordkeeping hours + 19,380 reporting hours)

The total recordkeeping burden for NRC licensees = 24,613 hours plus the total reporting burden = 19,800 hours for a total annual burden of 44,413 hours at a cost of $6,750,776.

Agreement State Licensees:

The total annual burden is estimated to be 3.4 times that of NRC licensees or

150,687 hours per year for the approximately 16,000 Agreement State licensees. The details are shown in Tables 3 and 4.

Cost for the Agreement State licensees @ $63/hour = $3,736,404 [59,308 hours (57,880 recordkeeping hours for Sections 30.41(c)&(d) and 30.51 + 1,428 reporting hours Sections 30.51(d)& (f)]

Cost for the Agreement State licensees @ $152/hour = $13,889,608 [91,379 hours (25,488 recordkeeping hours + 65,891 reporting hours)

The total recordkeeping burden for Agreement State licensees = 83,368 hours plus the total reporting burden = 67,319 hours for a total annual burden of 150,687 hours at a cost of $22,904,424.

The total Part 30 annual burden = 195,100 annual burden hours [107,981 recordkeeping hours + 87,119 reporting hours] for a total cost of $29,655,200.

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the records storage cost has been determined to be equal to 0.04 percent of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is insignificant, as shown below:

- 107,981 recordkeeping hours x $45 x 0.0004 = $1,944

14. Estimated Annualized Cost to the Federal Government

The annual cost for the NRC to review the records and reports required by 10 CFR Part 30 is estimated to be 9,834 hours x $152/hour, or $1,494,768. This cost can be broken down into: 7,609 hours, or $1,156,568, for review of the reports submitted to NRC; and 2,225 hours, or $338,200, for review of the records during inspections. The majority of the cost for review of reports is associated with review of the decommissioning funding plans and decommissioning plans, which account for 5,539 hours, or $841,928. In addition, technical assistance contracts for review of these plans are estimated at $100,000. Therefore, the total estimated annualized cost to the Federal government for the 10 CFR Part 30 information collection requirements is approximately $2,436,696. Application review activities for 10 CFR Part 30 licensees are attributed to and reported under OMB Clearance No. 3150-0120 for NRC Form 313. The burden of certifying the disposition of all licensed material, including accumulated wastes, required for termination of 10 CFR Part 30 licenses is reported under OMB Clearance No. 3150-0028 for NRC Form 314. These costs are fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall burden has increased by 38,470 hours from 160,919 hours to 199,389 hours. The increase is primarily due to the addition of 1 Agreement State and the

increase in the number of Agreement State licenses from 15,847 to 16,253. The estimated number of Agreement State licenses is expected to increased at a ratio of 3.4 times that of NRC Licensees.

The overall reporting burden increased by 28,464 hours from 58,930 hours to 87,394 hours because of the increase in the number of Agreement States licensees from 15,847 to 16,253, with a corresponding increase in the number of responses and burden for sections 30.35(a)&(b); 30.36(g), and 30.50. This burden also increased because of the incorporation of sections 30.51(d)&(f) and 30.55(c) which were inadvertently omitted from the last clearance package. While the overall burden for Agreement States licensees increased by 28,292 hours, the overall burden for NRC licensees increased by only 172 hours from 19,783 hours to 19,955 hours. Although the overall burden for NRC licensees increased by 176 hours, the burden per response for section 30.34(b) was reduced from 2 hours to 30 minutes, with a corresponding net burden reduction. The decrease in burden per response is based on NRC's re-estimate of the time required to gather and prepare the information required to notify the NRC of proposed license transfers.

The overall recordkeeping burden increased by 10,206 hours from 101,789 hours to 111,995 hours because of the increase in the number of Agreement States licensees from 15,847 to 16,253, and in the number of recordkeepers for sections 30.34(e)(4) and 30.34(g). Although the recordkeeping burden for Agreement States licensees increased by 13,208 hours (from 74,129 to 87,337 hours), the burden for NRC licensees decreased by 3,202 hours (from 27,860 hours to 24,658 hours), primarily because of the reduction in the number of license transfers and terminations for Sections 30.41(c)&(d) and 30.51.

There was a change in cost because the hourly rate increased from $121 to $152.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

The requirements are contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Table 1. Part 30 Reporting Burden for NRC Licensees

Section	No. of Respondents	Response Per Respondent	Burden per Response	Total Annual Reporting Burden (Hours)	Comments
30.9(b)	9	1	1	9	
30.11	20	1	5	100	
30.15(b)					Burden covered under OMB Clearance No. 3150-0120
30.18(d)					Burden covered under OMB Clearance No. 3150-0120.
30.19(b)					Burden covered under OMB Clearance No. 3150-0120
30.20(b)					Burden covered under OMB Clearance No. 3150-0120
30.32(a)					Burden covered under OMB Clearance No. 3150-0120
30.32(b)					Burden covered under OMB Clearance No. 3150-0120
30.32(f)					Burden covered under OMB Clearance No. 3150-0021
30.32(g)					Burden covered under OMB Clearance No. 3150-0001
30.32(i)	1	1	10	10	
30.34(b)	280	1	.5	140	
30.34(e)(4)					
New technology/ standard conditions	2	1	4	8	
Orders					Burden covered under OMB Clearance No. 3150-0120
30.34(h)	10	1	.5	5	
30.35(a)&(b)					
Certification	50	1	100	5,000	

Funding Plan	15	1	300	4,500	
30.36(d)	308	1	1	308	
30.36(e)					Burden included in Section 30.35
30.36(e)(2)	10	1	6	60	
30.36(g)	25	1	360	9,000	
30.36(h)					Burden covered under OMB Clearance No. 3150-0120
30.36(j)					Burden covered under OMB Clearance No. 3150-0028
30.37(a)					Burden covered under OMB Clearance No. 3150-0120
30.38					Burden covered under OMB Clearance No. 3150-0120
30.50	70	1	4	280	
30.51(d)	280	1	.5	140	
30.51(f)	560	1	.5	280	
30.55(c)	2	1	10	20	
Appendix A					Burden included in Section 30.35
Appendix C					Burden included in Section 30.35
Appendix D	4	1	1	4	
Appendix E	91	1	1	91	
Total Respondents	**1,737**				
Total Annual Reporting Burden Hours				**19,955**	

Table 2. Part 30 Recordkeeping Burden for NRC Licensees

Section	**No. of Recordkeepers**	**Annual Hours Per Recordkeeper**	**Total Annual Recordkeeping Hours**	**Comments**
30.32(i)	5	10	50	
30.34(e)(4)				
Conditions 22 & 23	222	.5	111	
Condition 164	2,800	.08	224	
Condition 165(i)	2,800	.08	224	
New technology/ uses standard conditions	150	.2	30	
Orders				Burden covered under individual clearance requests that are submitted as needed.
30.34(g)	75	17.3	1,297	
30.35(f)	5	1	5	
30.35(g)	560	10.0	5,600	
30.41(c)&(d)	186	4.0	744	
30.51	4,678	3.5	16,373	
Total Number of Recordkeepers	**4,678**			
Total Annual Recordkeeping Hours			**24,658**	

Total NRC Burden (Tables 1 and 2): 44,613

Table 3. Part 30 Equivalency Reporting Burden for Agreement State Licensees

Section	No. of Respondents	Response Per Respondent	Burden per Response	Total Annual Reporting Burden (Hours)	Comments
30.9(b)	31	1	1	31	
30.11	68	1	5	340	
30.32(a)					Burden covered under OMB Clearance No. 3150-0120
30.32(b)					Burden covered under OMB Clearance No. 3150-0120
30.32(f)					Burden covered under OMB Clearance No. 3150-0021
30.32(g)					Burden covered under OMB Clearance No. 3150-0001
30.32(i)	3	1	10	30	
30.34(b)	952	1	.5	476	
30.34(e)(4)					
New technology/ uses standard conditions	7	1	4	28	
Orders					Burden is covered under individual clearance requests that are submitted as needed.
30.34(h)	34	1	.5	17	
30.35(a)&(b)					
Certification	170	1	100	17,000	
Funding Plan	51	1	300	15,300	
30.36(d)	1,047	1	1	1,047	
30.36(e)					Burden included in Section 30.35
30.36(e)(2)	20	1	6	120	
30.36(g)	85	1	360	30,600	
30.36(h)					Burden covered under OMB Clearance No. 3150-0120

30.36(j)					Burden covered under OMB Clearance No. 3150-0028
30.37(a)					Burden covered under OMB Clearance No. 3150-0120
30.38					Burden covered under OMB Clearance No. 3150-0120
30.50	238	1	4	952	
30.51(d)	952	1	.5	476	
30.51(f)	1,904	1	.5	952	
30.55(c)	7	1	10	70	
Appendix A					Burden included in Section 30.35
Appendix C					Burden included in Section 30.35
Total Respondents	**5,569**				
Total Annual Reporting Hours				**67,439**	

Table 4. Part 30 Equivalency Recordkeeping Burden for Agreement State Licensees

Section	**No. of Recordkeepers**	**Annual Hours Per Recordkeeper**	**Total Annual Recordkeeping Hours**	**Comments**
30.32(i)	17	10	170	
30.34(e)(4)				
Conditions 22 & 23	755	.5	377	
Condition 164	9,520	.08	762	
Condition 165(i)	9,520	.08	762	
New technology/ uses standard conditions	510	.2	102	
Orders				Burden covered under individual clearance requests that are submitted as needed.
30.34(g)	255	17.3	4,411	
30.35(f)	17	1	17	
30.35(g)	1,904	10.0	19,040	
30.41(c)&(d)	632	4.0	2,528	
30.51	16,905	3.5	59,168	
Total Number of Recordkeepers	**16,905**			
Total Annual Recordkeeping Hours			**87,337**	

Total Agreement States Burden (Tables 3 and Table 4): 155,776