ISSUES IDENTIFIED IN REEVALUATION OF EXEMPTIONS OR INCLUDED IN SECY-97-291

A. Issues Related to Regulation of Both Byproduct and Source Material

1. Information on Impact of Regulatory Program on Public Health and Safety

Issue: Reporting requirements imposed on distributors of exempt products and materials do not result in submission of sufficient, timely, and informative reports for NRC to determine what products and how much byproduct material and source material is distributed annually for exempt use, limiting the agency's ability to evaluate the impact of these practices on public health and safety.

Possible Solution: The usefulness of information collected through reports of byproduct material in products and materials being distributed to exempt persons could be improved by changing the period of reporting to every calendar year rather than 5 years (and when filing an application for renewal or termination of the license). Specific licensing and annual reporting of commercial distribution of source material to exempt persons should be required (as planned under SECY-01-0072). In addition, the staff could improve the handling of the information once received by re-establishing a computer database.

Discussion: This change would provide product distribution information that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than under the existing regulations. Because the date of reporting for each licensee is different and the information is not necessarily reported by year (in the case of source material, there is no reporting), it is difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends in the market. Also, the information is not very current. Reporting annually would eliminate these difficulties and would not significantly change the reporting burden for these licensees. In fact, it would be more straightforward and easier for licensees to report on a routine annual basis. (Prior to 1983, annual reports were required; experience shows that there have been more implementation and enforcement problems under the current scheme than there had been with annual reporting.) Also, providing a standard format or a form and allowing electronic submission could make the reporting process more efficient and could improve the quality of the information. As a result, the NRC could better evaluate the doses to the public from exempt products and materials, as well as inform the public concerning such exposures. These changes would also provide a better basis for considering any future rulemaking in this area and in allocating NRC resources.

2. Obsolete Provisions

Issue: Some regulations could be removed, because they are obsolete, i. e., no products/materials are being distributed for use under certain exemptions. In some cases, there appears to be no inventory in use under the exemption. Among these, the exemptions for resins containing scandium and for ceramic tableware could result in significant doses if used.

Possible Solution: Delete exemptions for products that are no longer being used or manufactured, or restrict further distribution while allowing for the continued possession and use of previously distributed items. Candidate exemptions in Part 30 are those for: automobile

lock illuminators, balances of precision, automobile shift quadrants, marine compasses, thermostat dials, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells. Specific requirements for manufacturers and distributors of products that are no longer being manufactured or distributed could also be deleted. These include § 32.17 for manufacture or distribution of resins containing scandium-46 and the prototype test procedures for automobile lock illuminators in § 32.40. Additional obsolete exemptions in Part 40 are: glazed ceramic tableware; photographic film, negatives, and prints; and fire detection units.

Discussion: For those exemptions where significant doses are possible, this action would provide assurance that health and safety is adequately protected from possible future distribution. This change would also simplify the regulations by eliminating extraneous text. It would eliminate the need to reassess the potential exposure of the public from these products for possible future distributions of the products. Also, these products would no longer need to be considered when assessing the total potential doses to the public from multiple sources. Five of these are self-luminous products; thus, distribution for use under § 30.19 could be evaluated and authorized, if a renewed interest arose.

3. ALARA

Issue: Section 20.1101 requires each specific licensee to implement an ALARA program. Does the scope of that requirement include the consideration by a distributor of doses to the public which result from the licensee's distribution of products used under the exemptions? Should applicants for licenses to distribute exempt products be required to demonstrate ALARA in design of their products? Should licensees who distribute exempt products implement ALARA in the design of products on a continuing basis?

Possible Solutions: Clearly state the NRC's position and implement that position in the NRC regulatory program (clarification of ALARA requirement in Part 20). Require all applicants for a license to distribute exempt products to demonstrate ALARA in the design of products. Require licensees distributing exempt products to implement ALARA in the design of products on a continuing basis.

Discussion: It is appropriate to apply the ALARA process to the design of products for which the user is exempt from licensing requirements. However, most products being distributed for use under an exemption have been manufactured for many years. During that time, the industry has made technological improvements in products and their manufacture that have reduced doses. Therefore, further reduction in doses for most products may be difficult. Although such improvements are to be encouraged, the staff believes that the burden from requiring a demonstration of ALARA for all of these products in the licensing process may not be justified. It should, however, be clarified in guidance and/or inspection procedures that the specific licensee’s ALARA program should consider new developments in technology as they may impact ALARA in the design of products.

4. Application of Part 20 to the Use of "Exempt" Materials and Products by Specific Licensees

Issue: The regulations are not clear concerning specific licensees' responsibilities under Part 20 for materials/products which are clearly exempt from Part 20 when possessed/used by

non-licensees. For example, must the specific licensee control disposal of the “exempt” materials/products in the same manner that it controls disposal of radioactive material listed in its license? Most exemptions from licensing in Part 30 also exempt users from Part 20. (The inclusion of such an exemption only concerns specific licensees possessing exempt products.) However, §§ 30.14, 30.18, or 30.21 do not include an exemption from Part 20. Thus, specific licensees are told to dispose of exempt quantities (§ 30.18) as if they were licensed material.

Possible Solution: Develop a position based on a re-examination of the individual exemptions and reasonable intent. Identify those products or materials, if any, for which there should be some controls when used by specific licensees and clarify licensees’ responsibilities in the regulations. Rulemaking would be needed to implement this position as the interpretation is not consistent across all exemptions.

Discussion: The need for controls concerns whether or not certain categories of licensees may be able to circumvent the regulations that should apply. Manufacturers/distributors may need to dispose of “exempt” products/materials as radioactive waste if large amounts of material are handled, e.g., they may have large numbers of defective products to dispose of; thus, it may not be appropriate to allow uncontrolled disposal. The exempt quantities provision needs to be carefully crafted.

5. Labels and Instructions

Issue: In some cases, labeling or the inclusion of instructions may be required in order to provide information to the user (and possibly others) on the radioactive material contained and how the product can be safely used, with the assumption that this knowledge may impact doses received. However, there is also a policy question as to whether the user has a "right to know" that a product contains radioactive material. This latter rationale was the reason for many of the existing labeling requirements, such as those for smoke detectors.

Possible Solution: Determine policy and apply consistently in the regulations. If the Commission adopted a policy of providing information to the purchaser on a right-to-know basis, some exceptions may be appropriate. Possible reasons for exceptions might be: (1) the practicality of labeling either the finished product or packaging or (2) low concentrations of radioactive material are present inadvertently rather than purposefully, such as with exempt concentrations. A specific example, where both of these apply, might be irradiated gemstones, which result in very low doses from induced radioactivity not purposely present, and for which, requiring information to be provided to the consumer could be more difficult than for many products.

Discussion: The staff does not believe that removing any existing requirements in this area, even if unnecessary for providing information on safe use, would be appropriate, as this could have a negative impact on public confidence. When there is information that could be instrumental to the user reducing his/her dose, this information should clearly be required to be provided by the distributor. With respect to adding new requirements of this type based on “right to know,” it is difficult to predict if the overall effect on public confidence would be positive or negative. Initially, people finding out a product they have previously used contains radioactivity may tend to have negative effects. However, over the long term, making better information available to the public should have a positive effect. The staff recommends that

requirements should be added for the labeling of point-of-sale packaging for all products, and in some cases the product itself, to the extent practical, to inform consumers about radioactive material content and that the purchaser is exempt from any regulatory requirements. This would be an additional, though limited, expense to distributors, without a tangible benefit to society. Note, however, some industries have voluntarily developed consumer information about radioactive content of their products, their regulatory status as exempt from regulatory requirements, and/or safe handling instructions. Also, labeling of products can sometimes have the added benefit that when properly labeled products containing radioactive material are received at landfills, smelters, etc., the product can be more readily identified as exempt from regulation, thus reducing costs of responding to alarms.

6. "Frivolous" Products

Issue: One of the basic principles of radiation protection is justification of practice. This principle leads to restrictions on products for frivolous purposes. While the consumer product policy does not refer specifically to the concept of justification, it does include consideration of the degree of benefit or usefulness of a product to the public and indicates that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit. Also, there is an explicit exclusion in the class exemption for self-luminous products (§ 30.19(c)) of products primarily for "frivolous" purposes and of toys and adornments. Decisions on individual products to be used under this exemption are made in licensing actions and sometimes involve making difficult judgments.

Possible Solution: Provide a more consistent basis for regulatory and licensing decisions concerning the acceptability to NRC of consumer products for which minimal societal benefit is envisioned or specifically in interpreting the restriction against products for "frivolous purposes" in § 30.19.

Discussion: This issue presents a difficult challenge given the subjective nature of the judgments underlying such decisions. To the extent that greater consistency may be achieved in these decisions, this should be addressed in guidance rather than through changes to the regulations. The NRC's policy to exclude the use of radioactive material in "frivolous" products comes not only from the basic radiation protection principle of "justification of practice," but also an intent to minimize the number of widely distributed products, so as to better ensure that public doses are appropriately limited given exposure to multiple sources.

7. International Issues

Issue: There are products that are exempt from regulatory control in other countries, but not in the U.S. These are sometimes found being sold in the U.S. This primarily results from the differing judgments made concerning justification of practice by various regulatory authorities, e.g., the United Kingdom has authorized the distribution of key rings containing tritium.

Possible Solution: Increase controls on the import and sale of products that are exempt from regulatory control in other countries, but not in the U.S.

Discussion: It is difficult to completely control the import of unapproved products, although the number of such products obtained by the public is much lower than is the case for approved

products. The staff has not identified any regulatory change that would address this difficulty. Some aspects of the staff's enforcement efforts in this area are discussed in SECY-02-0013, "Issues Concerning Self-Luminous Tritium Consumer Products," January 17, 2002.

8. Exempt Distributors in Agreement States

Issue: A distributor of exempt byproduct material in an Agreement State must have two licenses, a distribution license from NRC and a possession and use license from the State. When the requirement for an NRC distribution license for source material is added (as planned in SECY-01-0072), the same thing will be true for distributors of source material. There may be some inefficiency connected with this. Also, some States have questioned their need to license distributors who are also NRC licensees.

Possible Solution: Expand the NRC exempt distribution license to also cover possession for importers, so that there is no need for a separate possession and use license, particularly when no on-site testing is required. In the case of manufacturers, explore the possibility of allowing for the option of NRC licensing possession and use in Agreement States, in addition to distribution, at the discretion of the individual State.

Discussion: If there is no in-plant safety concern in the case of importers, the distribution license should cover possession. For manufacturers, the responsibility for licensing the facility is within the authority of the State; however, some efficiency may be gained from a distributor being subject to licensing by NRC only. This would be negotiated with the Agreement States.

9. Should the Requirement for SS&D Registry Be Made Explicit?

Issue: Section 32.210 provides only for voluntary registration for specifically licensed products, yet registration of many specifically and generally licensed and exempt products is required as an administrative practice, and fees are assessed based on whether or not a "sealed source and/or device review" is required. The products in each of these categories for which this is applicable are indicated in guidance. Also, there is no provision comparable to § 32.210 in Part 40 related to the Sealed Source and Device Registry. Administrative practice has resulted in the inclusion of a small number of devices and sources containing source material in the registry.

Possible Solution: Make registration requirement explicit in the regulations governing byproduct material, so that it is easier for potential applicants to determine the applicable requirements and associated fees. Add a provision to Part 40 similar to § 32.210.

Discussion: The regulations include requirements for information to be submitted by applicants and for determinations to be made by the NRC staff, which form the basis of the sealed source and device review and resultant registration. However, as a matter of licensing practice, applicants/licensees must obtain sealed source and device registration certificates for most, but not all, sources and devices. The regulations should be explicit concerning this process, so that it is easier for potential applicants to determine the applicable requirements and associated fees. The rulemaking process will include providing an explanation of the rationale for using a registration process as a licensing mechanism and will likely involve some reexamination of the basis for determination of which products should be included in the Sealed Source and Device

Registry. Not only will the regulations be more explicit and understandable, but there will be better assurance that there is a sound basis for the inclusion of devices and sources in the registration process.

B. Other Issues Related to the Regulation of Byproduct Material

1. Prescriptive Requirements for Distributors of Generally Licensed Devices and Exempt Products

Issue: The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing, sampling, and quality control. The regulations could be made less prescriptive and continue to contain general requirements and may provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures. In the case of generally licensed products, regulations that are possible candidates for modification include:

Prototype test procedures (§§ 32.53(d)(4), 32.57(d)(2), 32.101, 32.102, and 32.103)

Specified sampling or testing procedures (§§ 32.15(a)(2) and (3) and (c)(2), 32.55(a) through (d), 32.59, 32.62(a) through (e), and 32.110)

The only such prescriptive requirement pertaining to manufacturers of an exempt product is § 32.40, which is also obsolete; see item A. 2. above.

Possible Solution: Revise these paragraphs to make the requirements for distributors less prescriptive. The revision of the following guidance document would include example acceptable approaches: NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees."

Discussion: Less prescriptive, more flexible regulations would be more performance-based. The licensee would be free to propose alternative methods to those presented in guidance to satisfy the requirement in the regulation. The requirements would continue to provide adequate assurance that the products being distributed meet performance standards. Note, some of these requirements may instead be candidates for elimination under the following issue.

2. Make the Requirements for Distributors of Exempt Products More Risk-informed

Issue: The level of control on the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing, sampling procedures, and quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. There are currently no requirements in the case of distributors of source material. Each requirement should be reviewed based on the risk presented by the individual product.

Existing requirements for distributors of byproduct material to exempt persons include:

Prototype test procedures (§§ 32.14(b)(4), 32.22(a)(2)(xi), 32.26(b)(11), and (12)),

Sampling procedures (§§ 32.15(a)(2) and (3), and 32.110)

Submittal of quality control procedures (§§ 32.14(b)(5), 32.22(a)(2)(xv), 32.25(a), 32.26(b)(15)).

The staff does not believe that any similar requirements for submitting such procedures for generally licensed devices are candidates for revocation based on risk, as the safety of these devices relies on the design to a greater degree than exempt products.

Possible Solution: Eliminate individual requirements if not justified, based on risk. If appropriate, add requirements for some products containing source material.

Discussion: Unnecessary regulatory burden on distributors of byproduct material would be reduced. Adequacy of prototype testing and quality control for products containing source material have not yet been evaluated. A consistent approach should be applied in also determining whether any of the source material products should have such requirements.

3. Exempt Quantities - § 30.18

Issue (1): The NRC issued the exemption in § 30.18 based, in part, on the safety properties inherent to a single exempt quantity; however, later an NRC position had endorsed gauge manufacturers' distribution of gauging devices with a source holder, but without sources. The customer was then instructed by the manufacturer/distributor to obtain and insert multiple "exempt" sources into the source holder and enjoy the use of a gauge without regulatory control. The NRC subsequently withdrew its approval of such distribution of gauging devices and by letter so advised the gauge manufacturers. There appears to be a need for clarifying the regulations concerning NRC's position on combining exempt quantities.

Possible Solution (1): Clarify the regulations concerning NRC's position to preclude combining multiple exempt quantities so as to prevent circumvention of the basic safety properties relied on in the issuance of the exemption in § 30.18.

Discussion (1): Although a letter was sent to distributors to stop this practice (Generic Letter 99-01), the regulations should be clarified to preclude combining or bundling exempt sources. The radiological assessment shows there is a potential safety hazard if multiple exempt sources (for some radionuclides) are combined and used in a device. Both of the objectives of risk-informing the regulations and protecting the health and safety of the public can be achieved with the proposed solution.

Issue (2): Recommended dose calculational methodology has changed since the establishment of this exemption; thus, the various nuclide quantity limits present significantly different potential doses. Also contributing to the range of potential doses associated with the individual radionuclide limits is the approach to controlling external vs. internal doses, whereby

radionuclides that present an external hazard tend to present higher potential doses than those that present primarily an internal hazard.

Possible Solution (2): Update the tables in § 30.71 to reflect the dose limits in Part 20 and the most up-to-date data on radionuclide uptake and metabolism as a basis for setting limits to control internal doses. Also, use a somewhat more restrictive approach to controlling external doses. Alternatively, identify the specific radionuclide limits with the highest potential doses and selectively reduce those limits to maintain the appropriate level of risk.

Discussion (2): This would maintain the overall intended level of risk, while equalizing the level presented by the individual quantity limits for the various radionuclides and reducing the maximum potential individual doses. However, this would involve significant effort and a relatively small number of the radionuclides are actually distributed for use under this provision. Thus, there may not be a net benefit from a complete revision of the table in § 30.71. In addition, the Commission recently approved not moving forward with rulemaking to reflect current ICRP recommendations at this time. (SRM dated April 12, 2002, on SECY-01-0148) The alternative approach would do much of the same with respect to the radionuclides presenting the highest potential dose, mostly involving external dose.

4. Exempt Concentrations - § 30.14

Issue (1): Lack of assurance that the allowed concentrations and other conditions for issuance of the specific license authorizing distribution of materials for possession under § 30.14 will not result in individual members of the public receiving doses greater than a small fraction of 100 mrem/year (1 millisievert/year); even doses in excess of 100 mrem (1 millisievert) in a year are possible, although not occurring under present practices.

Possible Solution (1): Add a requirement that the applicant for the specific license authorizing the introduction of the byproduct material in exempt concentrations must, in addition to present requirements in § 32.11, provide reasonable assurance by means of appropriate scenarios, measurement data and calculations that the dose to an average member of the critical group of the public will not exceed certain safety criteria. In this case, this might include a routine dose limit of 1 mrem/year (10 μSv/year), as the byproduct material usually serves no purpose in the product/material, but arises as a result of a production process. The new rule could also set out conditions for granting of exceptions to this dose limit.

Discussion (1): Although based on current trends in distribution, actual doses do not appear to be approaching 100 mrem/year (1 mSv/year), and are generally much lower, the evaluation for exempt concentrations indicated the potential for doses that are inappropriate for exemption, possibly even exceeding the annual public dose limit of 100 mrem/year (1 mSv/year) under routine conditions. Better assurance is needed to prevent inappropriate exposures under this exemption.

Issue (2): The exempt concentrations in § 30.70 are based on out-of-date technical data. These concentrations are generally based on the same scientific information on radionuclide uptake and metabolism and dose limits that served as a basis for concentration tables in Part 20 as published by the AEC in 1960. The revised Part 20, effective no later than January 1, 1994, is based on more recent information on radionuclide uptake and metabolism

and revised dose limits. Many entries in the concentration tables in the revised Part 20 differ from those in the earlier tables of 1960. Accordingly, there is no longer consistency between the exempt concentrations in § 30.70 and the revised Part 20. This lack of consistency between § 30.70 and the current Part 20 raises a question about the adequacy of the technical basis for the exempt concentrations in § 30.70. Also, newer dosimetry (ICRP 72) would result in somewhat different dose estimates.

Possible Solution (2): Update the concentration tables in § 30.70 to reflect the radionuclide uptake and metabolism models on which Part 20 limits are based or use current technical data and ICRP recommendations as a basis.

Discussion (2): There are complex issues related to the exempt concentration provisions and a number of approaches that may be taken to address these issues. Until these are explored in more detail, it is difficult to determine whether there would be a net benefit from a complete revision of the tables in § 30.70 (as well as § 30.71, Exempt Quantities) to reflect a more consistent level of risk, based on the latest dosimetric methodologies. Doing so would leave these tables of nuclides inconsistent with Part 20. In addition, the Commission recently approved not moving forward with rulemaking to reflect current ICRP recommendations at this time. (SRM dated April 12, 2002, on SECY-01-0148)

Issue (3): Section 32.11(c) requires, among other things, that the applicant for specific license provide reasonable assurance that "...the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being." Under general authority provided in § 30.11, exemptions to this provision have been granted by the NRC for irradiated gemstones. The regulations could be more specific concerning the information and showing to be made by an applicant in requesting exemptions to this prohibition.

Possible Solution (3): Consider amending § 32.11 and revising NUREG-1556, Vol. 8, “Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Exempt Distribution Licenses” to: (a) advise the license applicant of the information to be submitted when seeking an exemption to the above requirement, and (b) set out the NRC’s criteria for granting the requested exemption. Another alternative would be to remove or revise this restriction. It is primarily for the purpose of not interfering with the responsibilities of the FDA, although it is also consistent with the Commission’s Consumer Product Policy indicating that toys, novelties, and adornments are considered of marginal benefit.

Discussion (3): Such information with respect to gemstones specifically is already contained in NUREG-1556, Vol. 8, “Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Exempt Distribution Licenses.” The only other practice for which this had been considered is the use of explosives detection devices at airports that involves neutron irradiation of cargo and baggage using Cf-252. This system was developed in the 1980's but is not currently licensed by the NRC. Additional guidance could be developed, if needed. Developing a generic provision for addition to the regulations may not be cost-beneficial.

5. Class Exemptions for Self-luminous Products and Gas and Aerosol Detectors

Issue: In §§ 32.24 and 32.28, safety criteria are stated in terms of whole body and organ doses consistent with ICRP 2 recommendations rather than Total Effective Dose Equivalent (TEDE) as used in Part 20, and more recent recommendations on dose calculational methodology.

Possible Solution: Revise §§ 32.24 and 32.28 and related sections to remove the specific organ dose criteria and state the criteria in terms of TEDE.

Discussion: Although this use of whole body and organ dose limits has been effective in controlling doses to the public, the use of TEDE limits would be consistent with the NRC's basic radiation protection standards in Part 20 and its consideration of dose to individual members of the public (see § 20.1301). Note: Part 20 specifically defines TEDE to include deep dose equvalent for external doses; however, the Commission has interpreted Part 20 to include discretion for the use of effective dose equivalent for estimating external doses. The use of TEDE dose criteria, which reflect overall risk, without separate organ limits, are considered adequate to protect public health and safety for this application. The use of TEDE in §§ 32.24 and 32.28 and related sections would facilitate comparison of these limits with the limits in Part 20. Such consistency may contribute positively to public confidence. This would also result in a small increase in efficiency, effectiveness, and realism.

6. Establish a New Class Exemption for Certain Industrial Products

Issue: Specific or general licenses now used for products such as H-3 and Ni-63 chromatography units, gauges using small beta sources, and internal calibration sources provide overregulation and unnecessary expenditure of user and NRC resources.

Possible Solution: Establish a new class exemption, with associated safety criteria for these and similar products. This might include x-ray fluorescence analyzers and static eliminators. As the potential doses cover a wide range, these products cannot easily be exempted across the board for any product in one of these categories. Licensing requirements for distribution of devices for use under the new exemption may be comparable to those now imposed on specifically licensed distributors of devices used under the general license in § 31.5 and the specifically licensed distributors of gas and aerosol detectors used under § 30.20. The applicant for a distribution license would be required to provide reasonable assurance that doses to users would be unlikely to exceed a small fraction of Part 20 dose limits for members of the public. If the new class exemption is limited to industrial uses, where the critical group is projected to be workers, and designed to avoid residential use, a somewhat higher dose limit might be included. Alternatively, the new rule could set out conditions for granting exceptions to the routine use dose limit. In either case, the licensing requirements would need to account for disposal and recycle concerns.

Discussion: For each of the various categories of licensed devices suggested for possible use under exemption and included in the dose evaluations of NUREG-1717, some of the devices would clearly result in doses so low that use under license would be considered an unnecessary regulatory burden and an unnecessary expenditure of user and NRC resources. However, it is not clear that each type of device would necessarily qualify for exemption for all of the radionuclides and quantities considered. A new class exemption, covering a broad range of

industrial products, could relieve these burdens, while maintaining health and safety. This would put the burden of demonstrating that a particular product meets the safety criteria on the applicant distributor (with NRC review and approval). Such a class exemption would also allow for the development of new products for use under exemption without the necessity for rulemaking.

7. Manufacturer's Modification of Product without Prior NRC Approval

Issue: As stated in NUREG-1556, Vol. 8, "...If any of the information provided in the original application (for license to distribute products to exempt persons) is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. ..." This is also the case for generally licensed products and some specific licensee programs and facilities. This requirement delays changes in products and their production and in licensees' programs and facilities. Some of the changes may be safety improvements or may maintain the existing level of safety but be cost saving. This issue was identified in SECY-97-291.

Possible Solution: Provide, within limits, flexibility for the licensed manufacturer/distributor to make changes in the product and its production. Section 50.59 provides for reactor licensees to make certain changes in the facility and procedures described in the final safety analysis report without prior NRC approval. By rule change or by administrative practice, a comparable provision for change could be afforded manufacturers of products. The Commission could consider revising Parts 30 and/or 32 to allow some byproduct material licensees to make changes to facilities, programs, or product designs without NRC prior approval, if they can determine that there will be no reduction in safety.

Discussion: Based on the history of a recent revision to § 50.59 and the broad range of products and facilities involved in the use of byproduct material, it may be a resource-intensive effort to develop an appropriate provision(s) for Parts 30 and/or 32. Thus, the staff is not recommending such a change in the regulations at this time. However, eliminating some unnecessary impediments to a licensee making changes that do not adversely affect safety has been addressed in licensing practice since this issue was identified. Also, due to changes made to the fee structure, fees for amendment of licenses are no longer a deterrent to licensees proposing changes. This issue can and should continue to be addressed as appropriate in the licensing and sealed source and device registration process.

8. Class Exemption for Gas and Aerosol Detectors - Unnecessary Limitations

Issue: Products similar to those allowed, but not quite fitting the "class" cannot be approved under this exemption. For example, drug detectors were rejected for distribution under this exemption because they were not "designed to protect life or property from fires and airborne hazards."

Possible Solution: Broaden the class exemption for gas and aerosol detectors (§ 30.20), to include other potential applications.

Discussion: This would allow other potential applications under an existing framework, which has safety criteria that adequately protect public health and safety.

9. Electron Tubes - § 30.15(a)(8)

Issue: Quantities actually used in electron tubes distributed for use under § 30.15(a)(8) are much lower than allowed, on the order of 1000 times less.

Possible Solution: Reduce the quantities of radionuclides allowed in electron tubes to be closer to quantities actually used.

Discussion: This change would be based on the as low as reasonably achievable (ALARA) principle. Also, the additional assurance of extremely low doses may also help to justify removing some requirements on distributors, such as prototype testing or using approved quality control procedures.

10. General Licensees and Part 20

Issue: General licensees under §§ 31.5 and 31.7 are exempt from Part 20 except for §§ 20.2201 and 20.2202. Some generally licensed devices contain quantities of radionuclides meeting the criterion in § 20.2201(a) for immediate notification if lost or stolen. There seems an inconsistency in the risk basis of allowing a device to be generally licensed when the loss or theft of which would justify immediate notification. It has, however, been suggested that, for certain radionuclides at least, the quantities of materials requiring immediate notification are lower than necessary given the associated risk.

Possible Solution: If the risk does not justify immediate vs. 30-day notification, exempt some or all § 31.5 and § 31.7 general licensees from § 20.2201(a)(i), leaving only a 30-day notification requirement.

Discussion: Although reevaluating the risk basis of the criteria in § 20.2201 overall may be useful at some point, it is not urgent, nor should it fall within the scope of the current rulemaking as it would extend the scope of this action too much. The situation for general licensees and specific licensees is sufficiently different, that it would not be unreasonable for specific licensees to be expected to call the Operations Center immediately concerning thefts or losses and general licensees within 30 days for the same quantities of radionuclides. Generally licensed devices are designed to be safely used by persons untrained in radiological protection, who would not be expected to have the same level of familiarity with the regulations as specific licensee personnel. None of the generally licensed devices present an imminent danger to health and safety; most are required to meet the safety criterion of no person likely to receive a dose in excess of 15 rem (whole body) under accident conditions; others generally present a lower risk. Also, generally licensed devices do not contain the types and quantities of radioactive material that are considered to be of concern for possible terrorist use in a radiological dispersion device. Further consideration will be made concerning the risks presented by less timely notification of loss or theft of generally licensed devices. As generally licensed devices meeting the requirement for registration are considered a potential problem for contamination if smelted, this aspect will also be evaluated.

11. Residential Smoke Detectors Distributed under Class Exemption

Issue: Residential smoke detectors represent a well established practice with consistency in the design of products and with extensive licensing experience, but are licensed under a class exemption requiring product-specific evaluation against safety criteria.

Possible Solution: Add a product-specific exemption to simplify licensing, from that currently used in connection with the class exemption for gas and aerosol detectors (§ 30.20), based on extensive licensing experience with the product.

Discussion: Experience with the product provides a basis for reducing burden. Specific radionuclide quantity limits consistent with current practice would provide the primary safety basis.

C. Other Issues Related to the Regulation of Source Material

1. Welding Rods - § 40.13(c)(1)(iii)

Issue: NUREG-1717 shows calculated individual doses of up to 800 mrem/year (8 mSv/year) for a dedicated grinder of welding rods and 500 mrem/year (5 mSv/year) for welders using alternating current (AC) and no local exhaust ventilation. Using ICRP-68+ dose conversion factors, these dose estimates would be roughly 100 mrem/year (1 mSv/year) and 80 mrem/year (0.8 mSv/year), respectively, rounding to one significant digit as was done in NUREG–1717. Using dose conversion factors for actual measured particle sizes, or to those applicable to an activity median aerodynamic diameter (AMAD) of 5 μm as now recommended by ICRP for calculating occupational doses, would reduce these dose estimates further. Also, welders in the U.S. rarely, if ever, use thoriated-tungsten for AC welding. Pure tungsten or tungsten with a small percentage of zirconia is typically used for AC welding, particularly for aluminum. The thoriated-tungsten begins to melt when using AC, and as a result, the weld is not a good weld. Doses to welders using direct current (DC) are roughly a factor of 25 lower than doses to welders who use AC. According to NUREG-1717, exposure could be reduced by a factor of roughly 10 if local exhaust ventilation is used. The most significant concern would be the few distributors whose primary job is to grind electrodes to customers' specifications. They may be secondary distributors and not licensed. This activity occurs only at a handful of places in the U.S., and most likely, local exhaust ventilation is used. They may also use automated systems, where inhalation of grinding dusts are significantly less. Therefore, the dose to dedicated grinders is expected to be less than 100 mrem/year (1 mSv/year). According to one manufacturer, approximately 10,000,000 thoriated-tungsten welding electrodes are distributed annually in the U.S. According to a major distributor, approximately 20% of those sold are pre-ground.

Possible Solution(s): (1) Require distribution by a specific licensee who would be required to package welding rods with instructions on the hazards associated with use and the precautions to be taken to adequately control those hazards, such as, for example, using local exhaust ventilation. (2) Given that there are now reasonable alternatives, using rare-earths, consider restricting further distribution of any thoriated welding rods for use under an exemption.

Discussion: The staff will give consideration to both these options; however, it appears that the first will be the most cost beneficial. Doses to the general public are likely to be very small. It is considered unlikely that welders, who are occupationally exposed, are likely to be operating under the worst conditions throughout the year. Thus, it is unlikely for them to be exposed to doses of 100 mrem/year (1 mSv/year) or more. The highest potential dose is to the dedicated grinder. Because of inherent conservatism in the dose estimates and the likelihood that some precautions, such as local exhaust or respiratory protection, or automated systems, are likely to be used at least part of the time, even the pregrinding of welding rods by distributors is unlikely to routinely expose workers to doses approaching or exceeding 100 mrem/year (1 mSv/year). If thorium does not in fact present unique benefits over alternative types of welding rods and the costs of changing over are limited, the trend toward replacing the use of thorium with rare-earth alternatives will continue, but without the possible disruptions caused by an NRC prohibition.

2. Glassware containing Not More than 10% Source Material - § 40.13(c)(2)(iii)

Issue: Uranium has been used in the production of fluorescent and iridescent glass. The use of source material to achieve a particular appearance presents a question of whether this benefit is sufficient justification for the doses. There are also products being distributed that are potentially used by children, i.e., small tea sets, marbles. NUREG-1717 estimates doses to individuals of up to 2 mrem/yr (0.02 mSv/year) for users of the glassware (assuming uranium at the exemption limit of 10% by weight). NUREG-1717 estimates a potential for 10,000 person-rem (100 person-Sv) to result over 20 years from the display of such glassware in public places, such as museums, of 100,000 pieces. Note: A particular color of yellow-green glass made with 2% uranium dioxide is identified by collectors as “Vaseline Glass.” Information on the internet about Vaseline Glass Collectors, Inc., a non-profit club organized in 1998, indicates that Vaseline Glass was primarily made from Victorian times up to just before WWII, but some is still being made today by at least five manufacturers. At least one manufacturer has been recently selling sets of dinnerware made of Vaseline glass. This website also indicates that Vaseline glass is typically 2% uranium. There is a possibility that additional types of glassware containing source material are being imported or manufactured.

Possible Solutions: Treat in the same way as glass enamel frit was treated in 1983-4. Prohibit further manufacture/distribution but retain the exemption for previously distributed items. Alternatively, require that the “point-of-sale” packaging inform the purchaser of the radioactive component of the product, giving the user the ability to choose whether or not to use a radioactive product. Also, limiting the exemption to decorative pieces, specifically restricting use in products likely to be used by children, or lowering the concentration limit, would limit individual doses, though potential collective doses would still be significant.

Discussion: The concept of justification of practice would tend to lead to a decision to ban further distribution of these glass products. However, as this is an existing industry, and individual doses are a small fraction of the recommended dose limit for the public, the impact on current distributors and on users who want this product should probably be considered. The estimated collective dose may be significant; however, it is calculated based on millions of individual viewers each of whom receives an estimated dose of 3×10^{-4} mrem (3×10^{-6} mSv). Also, the assumed 100,000 pieces on display in public places is one half of one year’s assumed annual distribution. It would seem unlikely that one half of all items produced would end up on display for an average of 20 years after its initial use in homes. As the value of and interest in

previously distributed items may increase as a result of a discontinuation of distribution, it may be some time before the number of items on display in public places is significantly reduced from the present number. Note also, although the estimated collective dose is high, it is made up of extremely small individual doses. Requiring distributors to be specifically licensed and report types and quantities distributed as planned in SECY-01-0072 would provide a better picture of the industry as the basis of considering a possible ban in the future.

3. Gas Mantles containing Thorium- § 40.13(c)(1)(i)

Issue: NUREG-1717 shows a calculated individual dose rate of 7 mrem/yr (0.07 mSv/year) for campers from gas mantles. This dose rate could be reduced if there were simple handling instructions that were followed. Final NUREG-1717 added an assessment of gas lanterns used indoors at vacation facilities and in permanent residences. The highest individual effective dose equivalent calculated and reported in NUREG-1717 is 200 mrem/year (2 mSv/year). This dose is to an individual exposed to the continued use of mantles in four lamps in a permanent residence (assumed to be the only source of light). As indicated in NUREG-1717, it is unknown how many people actually use gas lanterns containing thoriated mantles as their primary source of lighting.

Possible Solutions: Require that distributors of thorium gas mantles be specifically licensed and that the distributors label the mantle's packaging with handling instructions for minimizing inhalation and ingestion of thorium. At least one distributor has voluntarily provided safety instructions. Alternatively, prohibit further distribution of any gas mantles containing thorium.

Discussion: For the critical routes of exposure, the primary contributors to dose are radon and its progeny; the dose estimates for these scenarios are not likely to be reduced greatly by applying current dose methodology. Also, potential doses associated with the use of thorium gas mantles in residential lighting would not be reduced significantly by providing handling instructions. As the mantles used in residential lighting are unique designs, different from the soft mantles used in camping, it might be practical to limit further distribution to mantles used in camping lanterns and provided with handling instructions. However, domestic manufacture using thorium ceased some time ago, and no recent import has been identified. The only known distributor is distributing hard mantles used in decorative lighting and in much smaller quantities than had been estimated in NUREG-1717. Although there may still be some soft mantles being imported, the practice has severely declined in recent years. Thus, the impact of a complete prohibition on future distribution for use under the exemption may be minimal.

4. Optical Lenses containing up to 30% by Weight Thorium - § 40.13(c)(7)

Issue: Although routine exposures would not be expected to exceed 20 mrem/year (200 μSv/year) to television cameramen, 1 mrem/year (10 μSv/year) to typical users of 35-mm cameras, and 2 mrem/year (20 μSv/year) to more avid photographers, one factor in this is the assumption that concentrations do not exceed 10% by weight thorium. Up to 30% by weight thorium is allowed in the exemption. Also, there are thorium-coated lenses for which the regulatory status is unclear and for which a radiological assessment was not included in NUREG-1717.

Possible Solutions: Revise the exemption to allow only 10% by weight thorium. Additionally, consider clarifying regulatory status of thorium-coated lenses by specifically excluding them from the exemption or explicitly exempting them.

Discussion: Revising the concentration limit would be in keeping with ALARA and would provide better assurance that doses do not exceed a small fraction of the dose limit. However, little is known about the concentration in currently distributed lenses. It is possible that there is no current distribution of the types of lenses considered in NUREG-1717. Thus, the cost/benefit for reducing the concentration limit is not clear at this time. More information concerning the use of thorium-coated lenses is being collected by the staff. More information and analysis may lead to the conclusion that thorium-coated lenses are acceptable for use without a license. Also, reasonable controls, possibly other than a concentration limit for averaging over the lens, may be developed that could ensure the protection of health and safety of the public without significantly affecting the existing industries that use these lenses. If enough information is obtained to conclude that this is the case, an explicit provision for these lenses will be included in the Part 40 proposed rule. For efficiency and effectiveness and to ensure the protection of public health and safety, it is important to clarify the regulatory status of these lenses.

5. Depleted Uranium in Aircraft Counterweights - § 40.13(c)(5)

Issue: Although NUREG-1717 did not estimate significant potential doses from this exemption; PRM-40-28 and comments made by the petitioner on draft NUREG-1717 suggest that there is a significant problem with this exemption in that there is little or no control over proper transfer or disposal when the counterweights are no longer in service. A Regulatory Issue Summary (RIS) 2001-13 was issued on July 20, 2001, to clarify disposal options. A key point was that the counterweights should not be transferred to scrap dealers or recyclers who are likely to physically, chemically, or metallurgically process the counterweights as such processing would violate the restrictions of the exemption.

Possible Solution: Replace this exemption with a general license. The primary requirement would be that products be appropriately handled and disposed of when removed from service. In order to ensure this occurs, some tracking or inventorying may be required. Another option may be to revise the general license in § 40.25 to accommodate most depleted uranium products.

Discussion: The intent of these possible solutions would be to more completely control the disposition of these materials. However, how to do so without causing significant increases in the costs of disposal needs to be studied further.

6. Finished Tungsten- or Magnesium-Thorium Alloy Products or Parts - § 40.13(c)(4) and Aircraft Engine Parts containing Nickel-Thoria Alloy - § 40.13(c)(8)

Issue: The exemption in § 40.13(c)(4) includes restrictions on the ultimate disposal of the products or parts. This is inappropriate for an exemption, as it is very difficult to enforce such restrictions, and there are limited ways of informing users. The exemption states, in part, that it "shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part..." The term "processing" precludes parts containing

tungsten or magnesium-thorium alloy from being sent to scrap facilities as an option for disposition. In contrast, § 40.13(c)(8) does not contain such a restriction. Since the alloys regulated in both sections are similar and used almost exclusively in aircraft engine parts, it may be more appropriate to regulate them in a consistent fashion.

Possible Solution: Replace these exemptions with a general license, possibly combined with airplane counterweights. These products are used almost exclusively in aircraft, and many of the users would be the same.

Discussion: The intent of the possible solution would be to more completely control the disposition of these materials. However, how to do so without causing significant increases in the costs of disposal needs to be studied further.