An Analysis of Potential Regulatory Changes to the General Licenses

The Commission has authority to issue both general and specific licenses. A general license appears in regulations[1] and grants authority to a person or individual for certain named activities involving the licensed material. The fundamental difference between a general license and a specific license is that a general license is provided by regulation and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person, and a specific license is issued to a named person who has filed an application for the license.

The U.S. Nuclear Regulatory Commission (NRC) and Agreement States ensure the public health and safety differently for general licensees than for specific licensees. For general licensees, safety concerns are addressed generically by extensive regulatory review of the design of the device and the practices of the devices' manufacturer so that, even in accident scenarios[2], there is no unacceptable risk to public health and safety. This generic assessment focused on the device obviates the need to assess the user's proficiency with radiation safety practices. As a result, the requirements (and fees) for a person or individual operating under general license may be substantially less than for those persons or individuals operating under a specific license.

The NRC and Agreement States ensure protection of the environment similarly for general and specific licenses. In either case, the devices must be transferred to a properly-authorized specific licensee at the end of the device's useful life. Because of events resulting in radiation exposure to the public and damage to the environment and property involving generally licensed devices, those devices that pose a higher risk, if disposed of improperly, are subject to a registration system. Registration is required "for those devices considered to present a higher risk (compared to other generally licensed devices) of potential exposure of the public or property damage in the case of loss of control" (65 FR 79162), and has been in effect nationwide since 2004. The registration system has not been implemented in a uniform fashion amongst the States and the NRC. The issue of the general licensee registration compatibility is currently the subject of a request for compatibility category change filed by the Florida Department of Health and associated with a petition for rulemaking filed by the Organization of Agreement States (PRM-31-05).

Many factors may impact the security of radioactive material used by general licenses. Among the several types of general licenses, there is considerable variation in the requirements prior to the general licensee receiving the material, the reporting requirements placed on the distributor and the user, and other requirements that would impact the security of sources possessed under general license.

In most cases, there is no review of the facilities or personnel for a person or individual seeking to use generally licensed material, because no application is required. However, some general

---

[1]General licenses for byproduct material are found in 10 CFR Part 31, general licenses for source material are found in 10 CFR 40.20 through 40.28, and general licenses for special nuclear material are found in 10 CFR Part 70, Subpart C.

[2]10 CFR 32.51(a)(2)(iii)

licenses carry the condition that the general licensee must also possess a specific license. For other general licenses, the vendor cannot provide the product without first verifying that its customer has preregistered the device with a regulatory body. Other requirements may apply to the manufacturer – a specific licensee – for example, that certain devices must be installed by a vendor in the gauge's place of use.

The major assurances of safety of generally licensed material rely on requirements of each general license, such as radionuclide and quantity limits, and for others, the design and manufacture of the device. Generally licensed devices containing byproduct material are evaluated by the NRC and some Agreement States against safety criteria. The device must be designed so that a person or individual untrained in radiological protection can operate it safely. The shielding and containment of the licensed material must be designed so that the user will not be exposed to more than a fraction of the occupational dose limits. Accident scenarios are also evaluated. The generally licensed devices containing relatively large quantities of byproduct material therefore are heavily shielded and tamper resistant, for safety reasons.

As noted in NRC's rule implementing the general license registration requirement (65 FR 79161, December 18, 2000), individuals who possess devices under general license are not always aware of applicable requirements. Historically, the NRC has not contacted the majority of these licensees or inspected these licensees on a regular basis because of the relatively small radiation risk posed by these devices. If so warranted, the general licensees are subject to inspections, orders, and enforcement actions. As a result of the general license registration requirement rule, NRC has inspected general licensees more than in the past. However, the frequency of these is substantially less than for those persons or individuals operating under a specific license.

Reporting requirements vary amongst the several general licenses, and there is variation in the reporting requirements of the various Agreement State and NRC general licenses. As a result, the NRC has up-to-date data for some general licenses, and none for others.

In summary, considerable variation among the NRC's general licenses, which this Enclosure attempts to clarify. This enclosure presents the staff's analysis as follows. First, all general licenses are examined with respect to the International Atomic Energy Agency (IAEA) Categorization. Second, the general licenses with the potential to be a security concern are identified. Third, areas where increased regulatory oversight could be warranted are identified. Fourth, recommendations are made for rulemaking to amend the regulations governing the use and distribution of generally licensed sources.

General Licenses Provided by the NRC for Possession and Use of Radioactive Material

General licenses for byproduct material are found in 10 CFR Part 31, general licenses for source material are found in 10 CFR 40.20 through 40.28, and general licenses for special nuclear material are found in 10 CFR Part 70, Subpart C. Most general licenses are provided for particular radionuclides and subject to explicit activity limits. It should be noted that devices, not sources, are authorized for use under general license, but because the sources are contained within one housing, the devices are treated as if they were equivalent to the sum of their aggregated sources. Where applicable, quantity limits of the various general licenses are compared, in the following table, to the IAEA Categorization (Table 2-1).

Table 2-1 – General Licenses Providing Authorization to Use and Possess Radioactive Material under the Atomic Energy Act of 1954, as amended, and Their Correlation to the IAEA Categorization.

Radionuclide	**Regulation Providing the General License**	**Activity Limit**		**A/D Value** (From IAEA. 1 = Cat 3 and 0.01 = Cat 4)
		µCi	**TBq**	
Thorium-228	**§ 40.22**	5.6E+12	2.1E+05	up to Cat 1
Uranium-232	**§ 40.22**	1.5E+11	5.6E+03	up to Cat 1
Thorium-229	**§ 40.22**	1.5E+09	5.4E+01	up to Cat 1
Various (byproduct material)	**§ 31.5**	Unlimited	Unlimited	up to Cat 2, for practical purposes
Polonium-210	§ 31.3	500	1.85E-05	0.000308
Promethium-147	§ 31.7	300,000	1.11E-02	0.000278
Hydrogen-3 (tritium)	§ 31.7	1.0E+07	3.70E-01	0.000185
Selenium-75	§ 31.11*	200	7.40E-06	0.000037
Iodine-125	§ 31.11*	200	7.40E-06	0.000037
Iodine-131	§ 31.11*	200	7.40E-06	0.000037
Americium-241	§ 31.8*	5	1.85E-07	0.000003
Plutonium-236	§ 70.19*	5	1.85E-07	0.000003
Plutonium-238	§ 70.19*	5	1.85E-07	0.000003
Plutonium-239	§ 70.19*	5	1.85E-07	0.000003
Plutonium-240	§ 70.19*	5	1.85E-07	0.000003
Plutonium-241	§ 70.19*	5	1.85E-07	0.000003
Strontium-90 (Y-90)	§ 31.10	50	1.85E-06	0.000002
Hydrogen-3 (tritium)	§ 31.3	50,000	1.85E-03	0.000001
Hydrogen-3 (tritium)	§ 31.11*	Unlimited	Unlimited	very small**
Carbon-14	§ 31.11*	Unlimited	Unlimited	very small**

Note: General licenses not listed above include § 31.11 for iron-59, for which the IAEA has not yet published a 'D-Value', and § 40.25 for depleted uranium, for which the IAEA does not consider a dangerous radionuclide in any quantity. Any general license for radium-226 would be under § 31.5.
*The general licenses in §§ 31.8 and 70.19 are only available to specific licensees. The general license in § 31.11 requires a specific license or pre-registration.
**The term "very small" is used to contrast the "unlimited" quantities allowable under § 31.5, which could be a concern, to the "unlimited" quantities allowable under § 31.11, which are not a concern. Under § 31.11, several tens of millions of units will need to be aggregated to create a quantity which approaches the 'D-Value' for these radionuclides.

Occurrence of General Licenses Authorizing Greater than Category 3 Quantities

Viewed from the perspective of the IAEA Categorization – even considering general licenses authorizing the possession and use of unsealed material – only two out of all the types of general licenses authorize possession of material greater than a fraction of Category 4: §§ 31.5 and 40.22. It is possible for a person or individual to use and possess an individual Category 2 source within the authorization of these general licenses, to the extent that the regulations do not prohibit such quantities. Additionally, these general licenses do not limit the number of smaller devices that a person or individual may use or possess in one location, so that if aggregated, the devices collectively could exceed a Category 2 quantity. These concerns are greater for the general license in § 40.22, due to the very large activities allowable. The title of § 40.22, "Small quantities of source material," refers to the small amount of mass (or weight) allowable under its general license. In terms of activity however, the title may be misleading (see Table 2-1) because millions of curies of certain thorium isotopes could conceivably be authorized for possession and use under this general license.

A preliminary search of the general license tracking system (GLTS) which is only applicable to NRC's Part 31 general licenses has shown that either Category 2 or Category 3 quantities have been obtained by general licensees. Although there is no equivalent mechanism for searching for a large source possessed under § 40.22, a search of the sealed source and device (SS&D) registry shows that the largest known high-activity, isotopically-separated sources that have been reported to be possessed under § 40.22 are Category 4. Besides §§ 31.5 and 40.22, no other general license has the potential to reach the Category 3 threshold.

Proposed Changes to the General License in § 40.22

Theoretically, very large activities of thorium-228 and thorium-229 could be possessed under the general license in § 40.22, which allows up to 15 pounds of source material to be used at one time and up to 150 pounds of source material to be used in one calendar year. Under the current regulatory structure, it is possible for a source material general licensee to possess a Category 1 source. For example, a person may possess 10,000 Category 1 thorium-228 devices under the general license in Part 40. This is because the general license in Part 40 is bounded on a mass basis, not activity. Similarly, 80 Category 1 uranium-232 devices could be possessed under the general license in Part 40. This is because these radionuclides have very high specific activities. However, NRC records indicate that only small quantities of isotopically separated thorium-228 or thorium-229 have been available commercially. Therefore, as a preliminary thought prior to rulemaking and subject to change as a result of Commission direction and stakeholder input, the staff recommends that significant quantities of isotopically separated source material would be no longer be authorized under this general license.

The general license in § 40.22 differs significantly from that in § 31.5. The risks are controlled only by the quantity limits in terms of weight. It is not limited to material contained in devices, nor are there limits on the chemical or physical form. There are no reporting requirements on distributors, so that the identities of the general licensees are not provided to the regulatory bodies. Additionally, there is no tracking of these general licensees or the materials distributed to them. As a result, there is no mechanism to verify if any isotopically separated thorium-228, thorium-229, or uranium-232 has been distributed for use under this general license, and if so, which persons or individuals may currently possess this material.

In “Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License,” (SECY-01-0072), dated April 25, 2001, the staff recommended rulemaking to better control and track persons operating under the general license in § 40.22, as well as additional controls to ensure public health and safety during the use of source material under this provision. This rulemaking is assigned and tracked as RM#564.

In the staff requirements memorandum to SECY-01-0072, the Commission requested that the staff collect additional information to support such a rulemaking. One difficulty in collecting the information has been that, without a past reporting requirement for either distributors or licensees, the staff has had to resort to novel and voluntary means of gathering the needed information. The staff is scheduled to provide the additional information and recommendations to the Commission in November, 2006.

Staff has considered major revisions to source material licensing to increase the accountability of licensees using source material (See generally SECY-01-0072). Given that very large quantities of radionuclides of concern are theoretically permissible under the general license in § 40.22, and the regulatory framework is not as well-developed as for byproduct material, initial steps are recommended to effectively enhance the security and accountability of sources under § 40.22. Regulatory provisions could be included to ensure that significant quantities of isotopically separated thorium-228, thorium-229, and uranium-232 would not be authorized under a general license. If pursued in isolation, due to the current framework for source material general licensees, regulations specific to enhancing security are unlikely to be effective. One main reason is that there are no reporting requirements on distributors, so that the identities of the § 40.22 general licensees are not provided to the NRC; the NRC has no ability to identify the licensees.

The staff is not re-recommending the same option as in SECY-01-0072 (Option #4 was recommended at that time). At this time, the staff would like to build on another option in that rulemaking plan – Option #5 – which could be easily modified to enhance controls for the sources of highest concern held within the § 40.22 general license. Among other things, Option #5 in SECY-01-0072 included reporting requirements for distributors of source material and requirements for certain sources to be used only under specific license. Another difference between the prior recommendation and the present time is that the IAEA Categorization could be used as a basis to establish the limit for use under general license, rather than the staff expending resources to establish such a limit independently. Although considerable changes would have to be made to the regulations, the staff’s prior effort (having already produced a rulemaking plan in SECY-01-0072) could be used to expedite the rulemaking process, given that the rulemaking plan would only have to be modified slightly and not developed anew.

Potential Changes to the General License in § 31.5 and Manufacturer/Distributor Requirements in Part 32

Changes could be made to the general license provided in § 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,” by amending the reporting requirements, expanding the registration requirements, and instituting explicit activity limits. These changes would affect existing and future licensees. Changes to manufacturer and distributor requirements in Part 32 could be

made to limit what devices are distributed to general licensees in the future. The Commission has the authority to issue orders to general licensees. Normally, changes to the general licenses would be made through notice-and-comment rulemaking.

General Licensee Reporting Requirements

A § 31.5 general licensee possessing a Category 2 quantity of material would not have to report source transactions to the national source tracking system (NSTS). Because paragraph § 31.5(c)(10) exempts the general licensee from the requirements of 10 CFR Part 20, except for §§ 20.2201 and 20.2202, a general licensee possessing a Category 2 source would be exempted from reporting to the NSTS. This section of § 31.5 could be amended to extend the general licensee's reporting requirement to the NSTS, in the case that sources meeting the criteria for NSTS are possessed under general license.

As NSTS would operate on a source basis, and this general license is on a device basis, some clarification of terms may be helpful. No known sources approved for use in generally licensed devices exceeds the Category 2 threshold. However, there is at least one device, multiple sources, which has a maximum allowable total activity of the Category 2 threshold. There are two reasons to treat sources contained within generally licensed devices equivalent to the sum of its sources as opposed to the sources individually. First, because such sources are contained within a single device, the sources will meet any co-location or aggregation concerns equivalent to the sum of its sources. A second reason for treating a device as if it were equivalent to the sum of its sources is, for practical reasons, that a unique serial number is critical to the operations of the NSTS. Generally licensed devices have been assigned and labeled with a unique serial number. There is no guarantee that all sources contained within the generally licensed devices have been assigned their own unique serial numbers. Therefore, the sources could be difficult to track.

General licensees under § 31.5 are exempt from all of Part 20 requirements, with the exception of §§ 20.2201 and 20.2202 (reporting thefts and losses, and reporting incidents, respectively). In effect, this means that a Category 2 source possessed by a specific licensee would be subject to the requirements of NSTS, but a Category 2 source possessed by a § 31.5 general licensee would be exempt from the reporting requirements of NSTS. In order to ensure that any future expansion of NSTS would apply to any generally licensed device that meets the criteria for source tracking, the staff recommends that § 31.5(c)(10) be revised so that these § 31.5 general licensees would not be exempt from § 20.2207 (reporting of transactions involving nationally tracked sources). This change would lay the foundation for the future application of NSTS equally to sources whether possessed under general or specific license.

General Licensee Registration Requirements

The general license registration requirement applies to devices containing certain named radionuclides, however it does not compel registration for all radionuclides of concern. See Table 2-2. Section 31.5(c)(13)(i) could be amended to require registration of all radionuclides of concern. This provision is the subject of a request for compatibility category change filed by the Florida Department of Health and associated with a petition for rulemaking filed by the Organization of Agreement States (PRM-31-05).

Table 2-2 – Byproduct Material General License Device Registration Thresholds, IAEA Categorization, and Certificates Authorizing Distribution to General Licensees

Radionuclide of Concern (Byproduct Material)	**General Licensee Registration Requirement** (mCi)	**Registration Requirement A/D Value** (From IAEA. 1 = Cat 3 and 0.01 = Cat 4)	**Categorization of Largest Applicable SS&D Certificate**
Am-241	1.0	0.0006	Cat 2
Cs-137	10.0	0.0037	Cat 3
Co-60	1.0	0.0012	Cat 3
Cf-252	1.0	0.0019	Cat 4
Cm-244	1.0	0.0007	Cat 4
Am-241:Be	1.0	0.0006	Cat 4*
Ra-226**	0.1	0.0001	Cat 4
Sr-90 (Y-90)	0.1	<0.0001	Cat 4
Pm-147, Po-210	**none**	-	Cat 4
Gd-153, Ir-192, Se-75, Tm-170, Yb-169	**none**	-	none

Note: Plutonium and thorium isotopes, while radionuclides of concern, are not subject to registration because they are not byproduct material. Polonium-210 is shown because it is a nationally-tracked radionuclide.
*The largest active certificate for a Am-241:Be device is Category 4.
**pending rulemaking.

A search of NRC's records reveals that all existing Category 2 and 3 devices containing byproduct material are already subject to the current registration requirements in § 31.5(c)(13)(i). As shown in Table 2-2, of the radionuclides of concern that are not subject to registration, only promethium-147 and polonium-210 have a SS&D certificate greater than Category 4. Of the generally licensed devices approved for use in quantities greater than Category 3, only three radionuclides have been used: americium-241, cesium-137, and cobalt-60 (Table 2-3). Based on the activity to 'D' Value calculations, general license device registration is required for sources much lower than the Category 3 thresholds. Therefore, the staff does not recommend changes for radionuclides already required to be registered. The staff recommends extending the registration requirement to cover all other radionuclides of concern that are not currently registered, such as for gadolinium-153, iridium-192, polonium-210, promethium-147, selenium-75, thulium-170, and ytterbium-169. Such an expansion should also consider other radionuclides such as those shown "below the line" in Appendix I to the Code-of-Conduct as unlikely to be present in large sources (e.g. gold-198, cadmium-109, cobalt-57, iron-55, germanium-68, nickel-63, palladium-103, ruthenium-106 (rhenium-106), and thallium-204).

Table 2-3 – Sealed Source and Device Certificates Exceeding Category 3 Quantities, Approved for Use by General Licensees

Radionuclide	Number of Certificates Approving Greater than Category 3 Quantities	Active Certificates Approving Greater than Category 3 Quantities
Am-241	33*	12*
Cs-137	33	10
Co-60	4	3
Am-241:Be	1	0
All Others	0	0

Note: Totals include devices whose certificate shows evaluation for general license (G), both general and specific license (B), and if it is "unknown" whether the device is evaluated for general licensees (U). No "unknown" Category 3 certificates are active.
* Includes one device which holds multiple Category 3 sources which, if aggregated, exceeds the Category 2 threshold for americium-241. Staff is, with the Agreement States, examining this certificate and current users in order to determine the appropriate course of action.

The primary benefit of expanding the registration requirement for devices generally licensed under § 31.5(c)(13)(i) to cover all radionuclides of concern would be to ensure that, should such devices ever be distributed to general licensees, there would be enhanced general licensee accountability. A secondary benefit would be that all radionuclides of concern would be treated equally. As currently structured, requiring registration for some of the radionuclides of concern creates an incentive for users to acquire non-registered devices in order to avoid the registration requirements. Registering these devices would require an incremental increase in staff effort and contractor support, which would be offset by the associated fees. The current annual fee for generally licensed devices subject to registration is proposed as $730 per location of use or storage location.

General Licensee Activity Limits – Introduction

As shown in Table 2-1, there are no explicit activity limits in the general license provided by § 31.5. However, for practical reasons, no devices have ever been approved for use under the general license in § 31.5 in quantities greater than Category 2, and the sources in this device are all Category 3 sources. The regulations in Part 31 could be amended to prohibit the use or possession of sources, individually or in aggregate, by general licensees above an activity-based threshold. In effect, this would "cap" the general license in § 31.5. The distribution and manufacturing requirements for generally licensed devices under § 31.5 are found in Part 32.[3] Whereas changes to § 31.5, such as a "cap," would affect existing and future licensees, changes to regulations in Part 32 would only affect future distribution. Therefore, the analysis of costs associated with various threshold scenarios would be very similar to that presented above, less the transition costs shown for the first year.

[3]Particularly 10 CFR 32.51, 32.51a, and 32.52.

The staff examined smaller subdivisions of the IAEA categorization for the purpose of assessing the concerns that devices just below the Category 2 threshold would not be subject to source tracking. Zero devices were found containing a radionuclide of concern from 99% to 75% of the Category 2 threshold; there is no evidence that such devices have ever been in NRC jurisdiction under general license in § 31.5.

General Licensee Activity Limits – Number of Devices

The GLTS was searched for all records of devices that have been reported in the NRC's jurisdiction, and filtered for those devices containing radionuclides of concern in at least Category 3 quantities. Although this method provides the broadest representation of the types of devices used under general license, it may not be appropriate for other purposes. Agreement State licensees are expected to have similar distributions of devices and collectively are estimated to have more licensees by a factor of four times that of the NRC. Counts of generally licensed devices by IAEA Categorization are presented in Table 2-4.

Two concepts in Table 2-4 are somewhat novel: D-Units and Category 2.5. Along with the well established Categories 2 and 3, Category 2.5 is presented in Table 2-4 as a subcategory. Category 2.5 should be interpreted as one-half of the Category 2 threshold. The reason for including this level is that the data naturally support a conclusion that this level should be considered as optimizing oversight of licensed material with a minimum of regulatory burden, as shown below. D-Units are a way to uniformly compare the potential for radiological consequences between sealed sources containing different radionuclides of concern. As opposed to comparing total activity, where one curie of strontium-90 is equal to one curie of californium-252, D-Units compare the two sources in a way that is weighted with respect to radiological consequences in accordance with the IAEA Categorization. One D-Unit equates to a Category 3 source, and 10 D-Units equate to a Category 2 source, per the IAEA Categorization. For comparison, a gamma knife is a device containing 201 sources with an aggregate total of 44 TBq of cobalt-60, equivalent to 1,481 D-Units. Calculation of D-Units was done in accordance with the IAEA Categorization (see IAEA, RS-G-1.9, Annex 2), as a robust and logical basis for comparing the potential for radiological consequences.

Table 2-4 – Cumulative Number of Devices Possessed and Used Under General License In NRC Jurisdiction, by Various Thresholds (using records, not necessarily active sources).

Category Threshold	**Number of Devices**	**Activity** (TBq)	**D-Units**
Category 2 +	16	19	303
Category 2.5 +	18	20	316
Category 3 +	257	47	674

From Table 2-4, it is shown that "capping" the general license at thresholds of Category 3 would increase regulatory oversight for considerable quantities of radioactive material. It also shows that the Category 3 threshold also increases the number of devices subject to specific licensing. The data show that between Category 2.5 and 3 there is a logical break where the activity could be capped with reasonable incremental staff effort.

The regulatory efficiency of different scenarios is presented in Table 2-5. The regulatory efficiency – the number of devices regulated per unit of potential radiological consequences – may be a factor in determining the preferred general license maximum threshold. Using such a regulatory efficiency is an objective way to balance the benefits of increased oversight of radioactive material of concern with the resources that are necessarily required to bring about those benefits. Essentially, because the burden of such a change would scale proportionally to the number of devices, and the potential for radiological consequences is proportional to the number of D-Units, this is a measure of the relative effort required for specifically licensing incremental measures of radiological consequences.

Table 2-5 – Regulatory Efficiency of Various Thresholds for Requiring Specific Licensing for Generally Licensed Byproduct Material Under § 31.5. (Using records, not necessarily active sources.)

Incremental Category Threshold	**Incremental Number of Devices**	**Incremental Potential for Radiological Consequences** (D-Units)
Category 2 +	16	303
Category 2 to 2.5	2	13
Category 2.5 to 3	239	359

A threshold of Category 2.5 compares relatively well with a threshold of Category 2 and has the benefit of regulating more material by way of requiring specific licensing for more sources. From Table 2-5, it is shown that although there is slightly more potential radiological consequences from the sources between Category 2.5 and 3 as there are from the sources greater than Category 2 (359 D-Units compared to 303), there are also approximately 15 times as many devices (239 compared to 16). Therefore, based on this measure of regulatory efficiency, the effort required to regulate the generally licensed sources between Category 2.5 and 3 is approximately seven times as costly as the effort required to regulate the generally licensed sources greater than Category 2.

Intuitively, for any radionuclide, larger devices may pose more potential for radiological consequences than smaller devices, but if the smaller devices are present in very large numbers, the aggregated potential for radiological consequences may be greater for the many small devices than for the fewer, larger devices. Based on the analysis of the data presented here, it seems that if an explicit limit is to be placed on the general license in § 31.5, Category 2.5 will require specific licensing for the most material while at the same time maintaining an optimal level of regulatory efficiency.

General Licensee Activity Limits – Labor Expenditures

Specific licensee labor rates are estimated from the Fiscal Year 2007 budget. Due to the limitations of the data available for analysis, an accurate count of the devices still in service was not obtainable in the time allotted, so the data may overestimate the burden. It should be noted that multiple generally licensed devices may be used and possessed by a single person or individual; the staff's best estimate for an overall average is that about three devices are held by a one person or individual who would be required to apply for a specific license.

Requiring specific licenses for devices currently in use under general license will necessarily require more regulatory oversight. For each new licensee, the appropriate regulatory agency will have to approve the application, respond to license amendment requests, and renew licenses. Materials licenses are currently issued for 10-year periods. The new specific licensees would be inspected. Based on current licensing prioritization, and assuming the "new" specific licensees would be Priority 5 materials licensees, inspections would occur (nominally) on a five-year cycle. With experience and satisfactory licensee performance, the inspections could occur less frequently, and inspections may be made by telephone in the future. Labor costs for the NRC would occur in the first year, as the new applications are submitted, at approximately 0.008 full time equivalent (FTE) per application. Ongoing labor costs would be necessary to inspect the new licensees (0.014 FTE per inspection), renew licenses (0.007 FTE per license), and also to review applications that otherwise would not be required. Table 2-6 shows the costs per new licensee, given the current materials labor rate.

Table 2-6 – Labor Costs Associated With Specific Licensing Currently Generally Licensed Devices, NRC Jurisdiction Only.

General License Maximum Threshold	**Number of "New" Licensees*** (Upper Range)	**First Year Labor Costs**** (000's of $)	**Ongoing Annual Labor Costs** (000's of $)			
			Inspection (5 yr cycle)	Renewal (10 yr cycle)	New Apps (est.)	**Annual Total****
Category 2	5	**$7**	$3	$1	$1	**$5**
Category 2.5	6	**$9**	$3	$1	$2	**$6**
Category 3	86	**$125**	$44	$11	$25	**$80**

Notes: *The number of new licensees was generated by dividing the number of affected devices by three, to reflect that the new licensees are expected to possess multiple devices. **These costs should be viewed as an upper limit, and are limited by the data that is available at this time. The unit rates per licensee and proportions (ratio of one threshold to another) are accurate, however. Essentially all of the uncertainty is due to estimating the number of new licensees that would be created. License amendments are ignored by this analysis at this time, but would cost 0.0047 FTE per amendment, and so would only contribute marginally to the overall costs.

The costs shown in Table 2-6 are just the licensing costs for the NRC staff to specifically license current general licensees. Agreement States would have to expend FTE proportionally to the number of their affected general licensees. This analysis of labor costs associated with specific licensing of current generally licensed devices does not consider the costs borne by the general licensees, which could be considerable given the regulatory change (e.g. preparing and submitting a license application, hiring an radiation safety officer, complying with 10 CFR 19, 20, and 21, etc.).

Proposed Changes to the General License Distributor Requirements in Part 32

From the data collected so far, it appears that limiting the distribution of Category 2 and Category 2.5 devices for distribution under §§ 32.51 and 32.51a would effectively and efficiently prevent sources of concern from being distributed to general licensees. Such a change would

affect a small number of distributors. There are few active SS&D certificates that authorize such distribution, and staff estimates that only 11 vendors would be affected by such a change. It is plausible that the devices would be re-evaluated to use smaller sources or to inactivate certain certificates. Of these certificates, only one is issued by the NRC, so Agreement State cooperation is vital, especially for those jurisdictions where the 11 active vendors are located.

A change to limit the distribution of Category 3 sources does not appear to justify the additional costs associated with the change when evaluated relative to the costs associated with Category 2 and Category 2.5. An analysis of the SS&D certificates shows that approximately 54 unique vendors possess active certificates for generally licensed devices, and these vendors and other stakeholders could be consulted as part of any rulemaking to amend the generally licensed device distributor regulations.

The decision to amend § 31.5 in addition to Part 32 will have to balance several qualitative factors. Any proposed change to the general license in § 31.5, which applies to the device users, should consider the potential negative consequence that the devices would become unwanted at the time of the regulatory change. Besides the costs to the NRC, the licensees who have to apply for specific licenses will also be subjected to up-front and ongoing costs associated with the regulatory changes. As these costs would be significant relative to their current costs, it is possible that some of these devices will become unwanted. On one hand, if the only regulatory change is to prohibit the manufacturers from distributing certain devices to general licensees in the future, the existing devices already distributed would, in effect, be "grandfathered" and not subject to the same regulatory oversight as identical devices in the future. There could also be an incentive for existing licensees to retain their "grandfathered devices" longer than they would otherwise. Based on available data on NRC's licensees, the population of general licensees using Category 2 and Category 2.5 devices appears small enough that their regulatory status can be examined on a case-by-case basis. The NRC would have to work with the affected licensees and States to (1) determine if the sources in Agreement States have similar characteristics, (2) ensure that all such licensees are capable of ensuring the desired level of controls for their devices, and (3) determine if a disposition path exists for any unwanted devices as a result of these regulatory changes. This interaction would involve relatively few licensees, and could be completed within one year.

In conclusion, currently available information indicates that requiring a specific license for Category 3 sources is not necessarily ruled out by prohibitive NRC licensing costs. However, given that the majority – approximately 80% – of licensees who would be affected by a general license "cap" at the Category 3 threshold are licensed by the Agreement States, and only a few (no more than 25) vendors distribute such devices, the staff requests particular interaction with these stakeholders to gather data to confirm that such a cap would have moderate costs. Prior to any data collection efforts, an Office of Management and Budget (OMB) clearance would be needed to comply with Paperwork Reduction Act requirements. This data would be gathered within one year. The staff would support a requirement for a specific license for all devices greater than Category 2 or one-half the Category 2 threshold (Category 2.5), due to the very modest expected costs and relatively large benefits.

Summary, Consolidated Recommendations, and Resources

The general licenses provided by the NRC's regulations were examined in light of the IAEA categorization. Enhanced controls do not appear justified for most general licenses by this measure. The general licenses in §§ 40.22 and 31.5 are exceptions because they have the potential to authorize Category 1 and Category 2 sources to be used or possessed by general licensees.

The specific recommendations and resources needed to effectively prevent the use and possession of sources of concern under § 40.22 are detailed in Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License," (SECY-01-0072), dated April 25, 2001, and assigned under RM#564. That rulemaking plan estimates that the whole rulemaking (e.g. proposed rule and final rule) will require up to 4.75 FTE and $190,000 in total, spread over three fiscal years. As part of the recommended rulemaking, the staff recommended that a limit should be placed in § 40.22 to prohibit the use or possession of isotopically separated source material under this general license.

The specific recommendations for changes to the general license in § 31.5 are to (1) amend paragraph § 31.5(c)(10) so that byproduct material general licensees would not be exempted from the requirements of reporting to the NSTS (10 CFR 20.2207, as proposed), (2) expand the registration requirement to include all applicable radionuclides of concern so that every byproduct material radionuclide of concern is regulated similarly, and (3) limit or "cap" the authorization of greater than Category 2.5 activities of radionuclides of concern under this general license so that only specific licensees may use or possess the sources with the highest potential for radiological consequences. The impacts of a general license "cap" below a threshold of Category 2.5 should be further examined with State and stakeholder input prior to any specific recommendation for changes to the general licensed device manufacturer regulation in § 32.51.

The resources required for the changes to the regulations in Parts 31 and 32 would be due to rulemaking. Program costs and regulatory impacts will be estimated as part of the rulemaking process as the detailed amendments are developed. Therefore, depending on resource prioritization, such a rulemaking is likely to take 24 months. This effort is currently budgeted by the Office of Nuclear Material Safety and Safeguards for a total of 2.0 FTE and $60,000 in contracted technical support.