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General Comment

On behalf of the State of Illinois, Illinois Emergency Management Agency, we hereby submit comments on potential changes to 10 CFR 20.

Attachments

10CFR20 Comments

June 22, 2015

Secretary
U.S. Nuclear regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

RE: **OPPORTUNITY TO COMMENT ON POTENTIAL CHANGES TO 10 CFR 20, STANDARDS FOR PROTECTION AGAINST RADIATION (FSME-14-076)**

The Illinois Emergency Management Agency, Bureau of Radiation Safety (the Agency), hereby submits its comments on potential changes to the U.S. Nuclear Regulatory Commission (NRC) regulations in the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation." Generally, the Agency supports a greater alignment with ICRP 103. This change is a substantial undertaking but is long overdue and the Agency believes that technology and our commitment to ALARA demand it.

Issue #1-Updated Methodology and Terminology

It's definitely time to upgrade all the rules to a level that reflects the knowledge and technology of the time. Dose modeling in particular is a major portion of this change and as a result, things such as sewer disposals, effluent releases and intakes/uptakes will better represent public demographics. The Agency does not think the resulting introduction of new terms/vocabulary will be that hard to overcome (i.e., dose equivalent vs. equivalent dose, etc.) and really should present no additional costs as long as updates to our rules follow the currently accepted adoption process. The challenge will be in the 'Appendix B' tables where new ALIs, DACs and effluent numbers will have to be generated. With regard to rules associated with demonstrating compliance and reporting, a generic safety factor could still be built into the language of the rule which would still allow agencies to evaluate other potential sources of exposure to the population to determine if any additional dose limiting actions should be taken. In addition, not all of the factors that go into these calculations have been proposed, reviewed and established by the ICRP. It seems prudent to wait until the tables are prepared by the ICRP (expected between 2015 and 2020) prior to incorporating them into regulation, rather than 'generically' referring to these undeveloped values. Regarding specific NRC questions:

- **What are the implications of changing the NRC's regulations to specify ''total effective dose'' in place of the current term ''total effective dose equivalent"? (Q1-1)** The terminology change is not hard to overcome. Regarding costs, there may be some one-time training costs to inform the public and get staff up to speed (a special topic HP course may be warranted); however, publishing costs are low since rules are no longer printed. Dissemination by email and web notices will limit distribution costs.

- **If the NRC adopts the dose assessment terminology and methodology of ICRP Publication 103 (2007) in a future rulemaking, what time period should the NRC**

consider providing for implementation of the ICRP Publication 103 (2007) methodology and terminology? (Q1-2) Rule adoption is set at 3 years, and there is no reason why that could not be met for these associated changes, unless the ICRP takes an inordinate amount of time developing its dose conversion factors and models. Licensees should be allowed to adopt sooner, especially those who operate in multiple jurisdictions if they are across-the-board changes, and not selective elements.

- **How should the calculations of effluent concentration be modified to reflect advances in modeling that are now available? Views on age and gender weighted composite? (Q1-3)** Effluent calculations (and any other derived values) should be carried out using the International System of Units with 2 significant figures (the rule with traditional units could be presented as an alternative). This approach should allow licensees (and regulatory agencies) sufficient information to develop tables with traditional unit if preferred. Alternately, consideration could be given to including 'conversion factors' as table footnotes. The Agency recommends that close scrutiny of I-131, I-125, and H-3 be applied for potential environmental issues (these values are likely to be lower than those that are currently established). The Agency is in favor of age and gender-weighted dose coefficients to better represent public demographics.

- **How should the calculations of effluent concentration, currently in the 10 CFR Part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available? (Q1-4)** The derived limits should take advantage of the better modeling parameters and utilize an annual limit of 5,000 millirem/yr for occupational workers and 100 millirem/yr for identified members of the public. Licensees could also be allowed to take an alternate path: showing how routine operation is below one-half of the table value for a generic case study. 10 CFR 50 (for production and utilization facilities) already uses more restrictive dose limits.

Issue #2-Lense of the Eye

Science is definitely showing that current restrictions/limits for doses to the eye fail to meet the need for protection of workers with regard to cataracts, and these limiting values need to be revised significantly downward. Until shown conclusively otherwise, cataract formation should be dealt with as a threshold event and as such should be managed with prejudice. Users of radioactive materials are not the population most likely to receive these doses to the eyes; in fact, individuals associated with X-ray exposures are the most likely to receive these types of doses. The fact that corrective surgery is readily available and reasonably affordable at this time should **absolutely not** play a part in the consideration of the limit. Medical procedures are not considered 'protection' for any other dose limits and shouldn't be in this instance; medical correction is a reactive correction, not a protective measure. For most RAM applications, the use of eye shielding is not practicable and as a result, doses are measured by whole body dosimetry. This can continue and the results can be used with a derived algorithm to estimate the dose to the lens. In interventional radiology, attention will have to be given to physicians and associated staff that wears two dosimeters or only one dosimeter that is worn under shielding when lens of the eye doses are assigned. A strong public awareness effort should be made to encourage the use of shielding by this population, either as clear barriers at the radiography table,

or as glasses with side shields worn by the physician. Also, when facilities are remodeled or built, this should be a factor in their design. The problematic effect will be the artificial lowering of the whole body limit. This negative effect would have little impact on the majority of occupational workers that are currently below the ICRP limit, and the benefit derived from preventing unnecessary cataracts of the eye warrants the change in limits. Regarding specific NRC questions:

- **Is closer alignment or adoption of the ICRP Publication 118 recommendations regarding the dose limits to the lens of the eye appropriate given the scientific information now available? (Q2-1)** Even though there may be some dispute over the exact values at which cataracts are observed to occur (and even threshold vs. chronic), the fact that values are all lower than current limits should be enough to justify and warrant the downward establishment of the value, even if the limit becomes a de facto lowering of the overall whole body dose limit. There has always been a 'lowest limit' in radiation protection, and whether or not that is the whole body or just an organ or the lens of the eye makes no difference to the overall goal of ensuring doses are below the established limits (it only changes the focus of our attention). Until such time as the ICRP or NCRP can make an alternate recommendation based on additional research and revised science, the 10 rem in 5 years with no single year exceeding 5 rem is appropriate. By using 2 rem in a year as the regulatory limiting value, there should be sufficient conservancy present to help drive down the cumulative 50 rem lifetime lens of the eye threshold limit.

- **How should the impact of a radiation induced cataract be viewed in comparison with other potential radiation effects? (Q2-2)** The impact of a radiation induced cataract should be viewed as a failure to control exposures to protect the occupational worker. Access to medical care does not change the fact that the effect has occurred. Although readily corrected via surgery, the action to correct the physical effect would otherwise be unnecessary if the appropriate protective steps had been enacted. If the alternate justification is arrived at to take 'credit' for available medical care, doses to the thyroid would become inconsequential as replacement hormone therapy is available (and in fact for populations above 40 years, effects from doses to the thyroid are not worth preventing) as well as doses to the whole body and other organs which can be transplanted.

- **What mechanisms could be applied to keep the cumulative exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad)? (Q2-3)** Mechanisms to avoid the cumulative 50 rem dose are best incorporated into discussions regarding implementation of a formal ALARA plan by licensees and reporting of doses into a national database. Again, the use of 2 rem in a year as a regulatory limit instead of strictly following the ICRP recommendation of 10 rem in a 5 year period with no year to exceed 5 adds sufficient conservancy to help achieve the 50 rem lifetime cumulative dose limit, but additional dose management actions will be needed.

- **What methods should be allowed for measurement or assessment of the dose to the lens of the eye? (Q2-4**) Methods for assessment should include algorithm based means on unshielded whole body badges, established protection factors for PPE based on the

energy of radiation the worker is exposed to as well as dosimetry assigned to be worn with PPE (non-radiological) eyewear.

- **What methods should be allowed for recording dose when eye is protected? (Q2-5)** Protection factors to be assigned based on lead equivalents or similar should be allowed by regulation as established and confirmed by a national body, or at least allowed following review by the regulatory body on a case by case basis in much the same way as respirator protection factors are applied for potential respiration of airborne radioactive material.

- **What are the potential operational impacts of lowering the annual occupational dose to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)? Would a reduction in the occupational dose limit for the lens of the eye require changes in programs, procedures, practices (e.g., increased use of protective eyewear), or in-room shielding? (Q2-6)** Operational impacts are likely to be born both in terms of programmatic changes and equipment purchases, as the resulting effective reduction of the whole body dose limit comes into play. However, to most of the monitored population, as a regulatory agency, those costs are likely to be minimal as doses to the vast majority of these people are regularly less than 2 rem annually. Additional effort may be needed when licensees are queried, specifically on this aspect of their radiation protection program during license reviews or inspections. Changes to guidance and application forms as well as inspection note forms would be warranted. Another impact would be to reevaluate populations previously excluded or discounted for the "10% of the limit" analysis which drives down the monitoring threshold from 500 millirem/yr to 200 millirem/yr.

- **What are the potential impacts on State regulatory programs of a reduction in the occupational dose limit to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)? (Q2-7)** As done previously when the public dose limit went from 500 millirem/yr to 100 millirem/yr, States may choose to adopt separate limits for those exposures associated with RAM versus those associated with electronic products as a matter of expediency; however, for those who acknowledge the science supporting modification of the radiation control program, the impact is not to be taken lightly. Several states, including Illinois, chose to 'grandfather' such facilities which were built to design specifications using the older dose limit until such time as facility modifications warranted additional action. It's likely this practice will be repeated. Again, training of x-ray users, training of inspectors and potentially restricting work or modifying radiology areas would all bear an associated cost. Additional monitoring and training costs are likely for affiliated occupationally exposed workers who may also be exposed to these sources of radiation.

Issue #3-Embryo/Fetus

Under the advanced notice of proposed rulemaking, the limit will be moved down from 500 millirem over the course of the gestation to 100 millirem over the gestation period. The intention is to protect the unborn to the same degree as any other member of the general

public. There is a large amount of scientific data to support the fact that the adverse impact of radiation during the pregnancy occurs at lower levels than previously observed. Science currently projects that the fetus is at the most risk, for developmental effects from radiation, during the period of weeks 10 through 17 (In the same vein, shouldn't the patient release rule be modified to acknowledge this scientific data as well? This is not addressed.). The proposed rule recognizes the ease at which external doses can be measured and the difficulty associated with determining doses as a result of uptake/intake that are subsequently passed on to the developing embryo/fetus. There is also a concern regarding 'leveling the dose' over the period from the power industry since there are so many 'ups and downs' of anticipated work and rad levels which are not common to other RAM uses. There is also a repeat concern to address again from the previous 1990 rule change regarding limiting dose over the entire period versus over the period since the time of declaration, in terms of enforcement. Regarding specific NRC questions:

- **Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts? What are the potential implementation and operational costs? (Q3-1)** The Agency anticipates significant impacts from implementing this requirement particularly to those individuals who handle diagnostic medical and PET materials, and potentially to x-ray operators. This is a large population of individuals, so even small programmatic changes can have a large cost associated with them and in some cases would incur a large capital cost, since facility design changes would likely be involved (shielding, space usage/assignments, etc.).

- **Are there any benefits or impacts associated with applying the reduced dose limit over the entire gestation period, or only to the period after declaration? (Q3-2)** From a regulatory perspective, the Agency sees no benefit to assigning dose limits over the gestation period. We prefer to regulate the period following declaration. As regulators, we would not feel comfortable citing a licensee for failure to limit doses to 100 millirem in those cases where the value would have already been exceeded prior to the time of declaration. Some sort of allowance would have to be granted.

- **Are there any anticipated implementation impacts on recordkeeping if the dose limit to the embryo/fetus is lowered to 1 mSv (100 mrem)? What are the potential implementation and operational costs? (Q3-3)** We do not anticipate any implementation impacts on the recordkeeping requirements if the dose were lowered in that most, if not all, of the existing licensees already utilize the option of recording doses to the nearest millirem from their dosimetry reporting service (even though in some cases the values below 10 mrem are questionable). There may be costs incurred by the licensees to staff extra positions to cover these declarations.

- **Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP Publication 103 recommendation difficult in certain circumstances? (Q3-4)** This is not an issue for external dosimetry as that can be easily approached, but it is definitely an issue with regards to internal dosimetry. Whole body counting has distinct limitations for some low energy nuclides.

Alternative methods such as urinalysis or fecal analysis do not provide sufficient information relative to all pathways. The amount of error introduced into the resulting calculation can render the result essentially meaningless other than for magnitude of intake. There should be some additional tolerance added for these types of results.

- **Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data? (Q3-5)** The Agency has no database of dose distribution to declared workers available for reference, nor has past dose histories of these workers been collected in other 'non searchable' formats.

Issue #4-Individual Protection – ALARA

Issue four takes up the topic of ALARA planning as a formal requirement. This subject hints of the old Quality Management Program that the NRC had for medical licensees in the early 1990s, and the various ALARA Investigations that still exist at some medical facilities and licensees. This is actually more of a mandated formal 'audit' of the licensee's radiation safety program than that which is currently in the regulations. All of the NRC NUREG 1556 licensing guidance documents contain a sample 'audit' for the scope of activities at licensed facilities, and that is one portion of this topic. However, the real impact surfaces when you consider all the other changes that are being proposed and the fact that each one of them has a 'dose management' aspect to them. As a result, this issue really points out how some of the implementation measures must be watched and how preventative actions may be necessary. Although, the overall dose limit is not being changed from 5 rem/yr to 2 rem/yr at this time, it well could. Also, there is greater emphasis on the 50 rem lifetime limit; although, this has not made it to formal rule proposal status yet. However, since doses to the lens and doses to the fetus are likely to be changed and potentially a more restrictive implementation of doses to members of the public via effluents and releases put in place, dose management will become an important portion of the radiation protection program. The Agency believes a parallel patient release criteria should also be developed for non-family members/direct care providers.

All regulatory agencies should consider collecting dose histories on a periodic basis from all licensees and track the information such that we can assure that licensees are actively evaluating cumulative doses to employees from all sources. More importantly, we should be taking action for those employees who approach 2 rem during the course of a year to further limit their exposures in order to assure that doses average less than 10 rem over a 5 year period (performance based). The NRC experiences with NSTS and the LVS should be a starting point in that regard. It currently supports a limited format database of 'REIR' which the Agency believes should be expanded to accept this data from states on a 'pass-through' basis. If this does reach implementation stage, then serious consideration could be given to enforcing the 50 rem lifetime limit in regulation.

Dose management was a simpler process when employment habits were 'lifetime careers'. But in these days of multiple job changes and for many, multiple simultaneous jobs, dose management is extremely difficult. The NRC enforcement group has not interpreted existing rules as applying to all current employers but easily could if reviewed in a new light. If

so, it would be necessary to implement some type of personnel dose tracking similar to the NSTS or at least go back to the days of all licensees reporting doses to all employees. But without a full 'buy in' from agreement states to include doses to operators of x-ray, accelerator and cyclotron units, only a partial picture would emerge.

Alternately, instead of creating an information databank, licensees could be held accountable to ask their employees on an annual basis for a copy of their previous year's exposure histories from all employers in order to evaluate the cumulative annual doses received. For those licensees who approach a 2 rem annual total, heightened oversight would have to be implemented for their activities involving radiation for the next few years. Regarding specific NRC questions:

- **What are the implications of adding specific ALARA planning and implementation requirements? What changes to programs would be anticipated? What would be the potential implementation and operational costs? (Q4-1)** The addition of adding ALARA planning and review would not have an immediate effect on most licensees as those licensees that have ALARA issues, are currently implementing such a plan as part of JACHO or similar certification programs. If a licensee could demonstrate that no worker receives a dose in excess of 100 millirem/yr, the requirement for an explicit documented ALARA program could be dropped/waived.

- **What regulatory language should be used for an additional ALARA planning requirement, and what is the rationale for this language? (Q4-2)** The draft language could look like: "For licensees whose average annual dose to an occupational worker from regulated sources of radiation is more than 100 millirem, a documented review of the doses received by any individuals for the previous 5 years shall be conducted to ensure that no single year exceeds 5 rem and that no total dose for the period exceeds 10 rem"

- **How does each of the described methodologies for addressing when an individual approaches the cumulative dose for the year work for different classes of licensed use? What are the benefits and impacts of the various approaches to ALARA planning on the various types of licenses? (Q4-3)** An administrative control level should not be explicitly required other than the ICRP-103 recommendation. However, licensees should be allowed to adopt whatever mechanism it chooses to meet this goal/requirement be that a strict 2 rem/yr limit or a 'floating' 2 rem/yr average with a 5 rem max for any given year. Radiographers and steam generator technicians at the utilities may have concerns with the new methodologies.

- **Should licensees be allowed to establish different ACL's for different groups of individuals? Basis? (Q4-4)** Licensees should be allowed to establish multiple ACLs for various groups but none of these should be subject to regulatory oversight save for the 5 rem/10 year performance expectation.

- **How do the different methodologies discussed impact the ability of licensees to best address protection within their programs? (Q4-5)** Individually, the options presented

are somewhat onerous, the least of which is the 5 rem/10 yr. In order to make this "ACL" less so, allowing the flexibility to implement more conservative measures only for licensees who exceed 100 millirem/yr for their workers should limit the adverse impact of this requirement.

- **Are there other ways to evaluate occupational lifetime cumulative exposure that could be considered? (Q4-6)** Not any that we would consider more appropriate.

- **What are the potential impacts of requiring a licensee to account for exposure from concurrent employment with another licensee? Are there any dosimetry vendors that provide concurrent dose records? Should the NRC consider provisions that would require individual occupational workers to provide their occupational dose information in addition to requiring such information from licensees? (Q4-7)** Administratively, the impact of a concurrent employment exposure limitations would affect only a small portion of the regulated community. That group would likely be diagnostic medical facilities and to a lesser extent the medical facilities offering oncology care. Similar to the nuclear power environment, it's likely that those third party employers that provide a pool of part time radiologist technicians would also develop a dose tracking aspect to their services so that their clients (diagnostic facilities) could have ready access to the necessary data to demonstrate compliance with the rule.

- **Should States be allowed to use more restrictive or prescriptive requirements if NRC decides to use performance based approach? (Q4-8)** Unfortunately, states should be obliged to adopt whatever rule is developed since the effect of implementation will most assuredly have a transboundary effect. We support this effort because of our St. Louis Metro East and Chicago based licensees.

Issue #5-Metrification: Traditional vs SI Units

Issue five takes up the topic of "metrification". The NRC Commissioners have essentially already decided the main portion of this issue in that the traditional units must still be used in addition to the SI unit. However, the issue of a consistent policy has come up in that in some places SI are first and traditional in parenthesis and in other places, vice versa and in still other places where the guidance, rules or reports haven't been updated the traditional units are the only units present (App B to 10 CFR 20). The most significant effect is at the power plants on this one with regards to cost (i.e., cost for retraining, cost for changes to publications, cost for conversions of systems, etc.).

The Agency recommends listing SI first, followed by traditional. This may present a problem when it comes to tables (such as with the quantities of concern) in that you end up needing to be 'bilingual' and in many cases you'll need to carry extra significant digits to help with rounding to the traditional values or you'll need to publish the table twice once in each version. In the world of marketing, nuclear medicine and shipping, we are already bilingual. In the world of oncology and therapy, the units play no role to speak of since energy deposited is the unit of interest and not activity or dose. The science behind all our engineering and dose modeling is already

SI. It's time our regulations and reporting got there as well. The evolutionary process has been a long time coming, but the Agency believes we are ready for it particularly as we seem to have a 'clear break' between the old school that is retiring and the new school that is inheriting this issue. Regarding specific NRC questions:

- **Will promulgation of amendments to the 10 CFR part 20 regulations with dose limits and other measurements shown in dual units, with the SI units shown first, followed by the traditional units in parentheses, cause an undue burden or hardship upon any licensee or class of licensees? (Q5-1)** The promulgation of dual units with SI first will not create an undue hardship on any licensee that the states regulate (or class of licensee for that matter.) particularly if a 'projected due date' approach is taken for the various requirements and licensees are provided sufficient 'lead time'. The addition of SI, in some cases, and the total conversion in others is only a matter of computer coding and conversion that end users in the licensee realm will not be burdened with. As these dose management programs, radiopharmacy updates, report generators are upgraded and purchased they will represent only a small part of the capital cost.

- **Should 10 CFR 20.2101(a) be revised to allow licensees the option of providing records in SI units or in traditional units? Should licensees be allowed to provide reports in the units used in licensee records? Should licensees be required to record and report in both sets of units? (Q5-2)** Licensee's should be offered the opportunity to report and maintain records in the same format as the regulations; that is, SI first followed by (traditional) or to report in SI alone. Maintaining records in both formats is unnecessary unless the licensees opt to do it for internal convenience.

- **Q5-3 Should the NRC amend the appendices for 10 CFR part 20 to show values in SI units only, in traditional units only, or in both sets of units? (Q5-3)** With regards to the appendices to 10CFR20 as well as other regulatory guides, info notices, etc., the NRC should adopt a consistent approach of SI (followed by traditional in parentheses when offered) as the format of choice. As a matter of routine it is suggested that a foot note to all regulations, documents, etc. that include numerical values, have the associated conversion factor noted if traditional values are cumbersome or would significantly affect the volume of the printed document. It's understood that the values reported in traditional units are derived from the SI values. As such, additional 'significant digits' should be included in the SI values when published.

Issue #6-Reporting of Occupational Exposure

Issue six takes up the topic of Reporting of Occupational Exposure. This topic has the most moving parts from a regulatory standpoint in that for the NRC to develop 'risk based' rules, the single most important piece of data is not typically available to them, doses to workers. Dose is really the best measure of risk for radiation protection and the best means to determine adequacy of an implemented radiation protection program. Unfortunately, when 10 CFR 20 was last revised, the compatibility requirement for the routine submission of dose information was changed to a lower category where states could choose to continue this program or not. This becomes even more of a problem when its noted that the majority of licensees exist in the

Agreement States, which further limits the availability of data. Currently only industrial radiographers and some manufacturers/distributors in some Agreement States are required to submit data. To be useful, the data collection would have to be from all states and a much wider group of licensees, particularly those in the medical and academic areas.

As mentioned in Issue 4 concerning ALARA programs, this topic goes hand in hand with determining the level of need and success of the ALARA program and compliance with the dose reduction strategy that the IAEA is promulgating for the fetus, lens of the eye and routine occupational exposures. While it may be easy to say we should just have the dosimetry companies send their data to the NRC, the issue of 'categorizing' that data by type of use and individual become problematic. In addition, those facilities that have high turnover and instead do 'internal assignment' of dosimetry would have a much higher associated work load to send this data along to the NRC database (REIR). There could also potentially be the difficulty of doses due to x-ray or accelerator produced radiation being intermingled with that from RAM which is the only portion subject to NRC regulation. Various concepts should be discussed such as anonymous reporting of sentinel individuals or perhaps, population group reporting or a combination which takes into account a threshold value of at least 100 millirem whole body or 500 millirem extremity before individual reporting is necessary.

There is also the issue of data submission and management. Should states collect the data and 'pass it along' after screening the data? Should an 'NSTS approach' be taken where the requirement for submission is adopted by the States but the collection and handling be done by the NRC? Can 'release' of the data directly from the dosimetry provider be authorized by licensees in such a case and what would it take to implement that release? All options would appear to be viable with the burden being placed on different entities under each circumstance. As an Agreement State, the NSTS approach would appear to be the most beneficial to the State with least burden except to step in and enforce the participation when it does not occur as required. That said, one would hope that the NRC has gained valuable insight on the development and deployment of such a system since the NSTS was first envisioned. Regarding specific NRC questions:

- **What criteria should the NRC use to identify additional categories of licensees that should be required to submit annual occupational exposure reports in accordance with 10 CFR 20.2206(a)? (Q6-1)** The NRC should use the criteria of "schema code" or if not viable, license category as the criteria to identify addition groups of licensees that should submit data. Use of 'schema code' would enable the NRC to more specifically review doses associated with particular uses of RAM to develop risk based regulations.

- **What are the benefits of collecting occupational exposure information in one central database in order to assess the total annual occupational exposure of those individuals who work at more than one licensed facility or contractor facility during the calendar year and receive occupational exposures at these facilities? (Q6-2)** The advantage to collection of occupational exposure information in a single database for individuals who receive exposures from multiple licensees would be from a dose management and compliance aspect. Currently this information is not systematically collected or reviewed by licensees on any type of regular basis nor is it used for ALARA

planning since it is not available. If the dose limits are reduced or modified in the proposed manner, this will become an important associated issue. Commercial nuclear power plants already use a similar system that should be considered in this rulemaking.

- **Should Agreement States be required to adopt regulations that are compatible with the requirements in 10 CFR 20.2206? (Q6-3)** States should be required to adopt compatible regulations as the number of licensees has shifted from NRC dominated to AS dominated. As a result, the data to support any type of regulatory change whether to lift a burden or impose a new requirement in response to a perceived issue does not exist. Please see the above discussion regarding submission and management as part of this response.

- **Should the NRC consider a gradual expansion of the 10 CFR 20.2206 licensee reporting categories in a step-wise fashion (e.g., staggered compliance dates for different categories of licensees)? (Q6-4)** A gradual expansion of reporting categories is not a reasonable approach. From a regulatory standpoint this would prolong the period that those responsible Agencies would have to deal with resulting startup and compliance issues. Monitored doses for all categories of licensees are based on a calendar year and imposition of the rules should be married to the calendar year with allowance for collection, review, adjustments and reporting of the final doses to sometime in late spring early summer of each year.

- **What are the potential implementation and operational costs associated with expanding the occupational exposure reporting requirements? (Q6-5)** Costs of this requirement should not be minimized. Time spent to review the data, put it into a usable format and then have that data merged with the national database can be based on the NRC's experience with the NSTS and as a result the associated cost. Since a larger number of participants will naturally occur, the costs should be scalable from that experience.

<u>Questions regarding Cumulative Effects of Regulations</u>

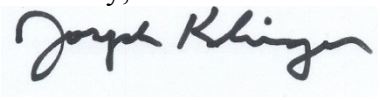
- **Because of CER what's a reasonable effective date for any potential 10 Part 20 revisions?** With part 37 and two distribution rules due over the next two years. Part 20 rules need to be put off at least until 2018 and until ICRP develops the appropriate appendices.
- **What could be done to address CER challenges?** Need to review prior regulations and determine if effective, necessary and enforceable. Many regulations and policies that are never looked at or enforced and should be dropped so that more current and relevant ones can be implemented and enforced.
- **What other actions could influence implementation of changes?** This is probably a good one to ask licensees in a survey and determine best methods for implementation.
- **Unintended consequences?** Regulations should not affect the quality of critical services. For example, patient care should not be compromised because of excessive regulations. Excessive regulations can also lead to apathy by licensees to the point where duties are simply completed for the sake of having a record rather than focusing on the

consequences of health and safety. For the most part, this ANPR is valid and has direct health and safety consequences.

- **Cost/Benefits available at this time?** Regulations drive costs up. The Part 20 proposed changes are necessary but will likely result in some elevated costs, especially in the medical industry for updating procedures, computer codes, training programs and some facility designs.

The Agency appreciates the opportunity to comment on this important document. If you have any questions, please feel free to contact Gibb Vinson at (217) 785-9928 or via e-mail at Gibb.Vinson@Illinois.gov.

Sincerely,



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