

MARYLAND DEPARTMENT OF THE ENVIRONMENT
AIR AND RADIATION MANAGEMENT ADMINISTRATION
RADIOLOGICAL HEALTH PROGRAM

FACSIMILE TRANSMITTAL SHEET

TO: Fred C. Combs
Deputy Director

FROM: Ray Mankin

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COMMENTS:

Additional NPI information

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January 11, 1995

JAN 13 1995

VIA FAX - 410-631-3198

Mr. Roland G. Fletcher, Administrator
Radiological Health Program
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Mr. Fletcher:

Thank you for inviting us to comment informally on the draft of MDE's proposed regulations prior to publication for formal comment. In order to be as constructive as possible, we have organized our comments into three parts.

1. As you know, we believe that NRC regulations are excessively stringent to the point that it has failed to achieve the balance required by the Atomic Energy Act. Our efforts to persuade NRC to remedy that situation are properly addressed in another venue; and the comments which follow are based on the premise that both MDE and Neutron are required to satisfy existing NRC regulations until they are changed.
2. Notwithstanding the shortcomings we perceive, NRC policies and practices offer licensees some protection against regulation that is arbitrary and capricious; and we believe that Maryland licensees are entitled to no less than equal protection in that regard. As you know, we believe that we have been illegally denied such rights and privileges in the past; and it is our opinion that the Agency's proposed Regulations tend to exacerbate, rather than remedy that error. Although we recognize that our comments in that regard may be more constructively heard elsewhere, as a matter of courtesy, we think we should give you an opportunity to consider them if you wish, and for that purpose, we suggest a meeting with you and others in MDE management.
3. Thus, the remarks which follow in this letter and its attachment are addressed primarily to the nuts and bolts of the draft Regulations for which our comments were solicited.

Comments as to Form

The effort required to analyze the proposed regulations and their prospective impact on Neutron, the public and other licensees was severely encumbered by the manner of presentation and the lack of a preamble that justifies the changes from the existing COMAR regulations and the new NRC Regulations. Early in your rule making process, our comments were invited; and we suggested that the new COMAR Regulations incorporate the applicable NRC Regulations by reference, taking note of, and justifying, any differences. Our effort to comment on the draft simply reinforced our views in that regard.

If MDE must issue a set of regulations which stand on their own, we believe that due process and common courtesy to the public, Maryland licensees and their employees require you to identify and justify each change to the existing COMAR Regulations and each departure from the new NRC

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Regulations being implemented. Otherwise, each interested party must undertake, at its own expense, the burden of comparing hundreds of pages of documents; and inquire or speculate as to the purpose, intent and effect of the changes being proposed.

The NRC performs such an exercise in a preamble to its notices of proposed rule-making, and we strongly recommend that the Agency do the same.

Comments as to Substance

We are not opposed to the regulation of atomic energy, either in principle or practice. Rather, we consider constructive regulation to be of prospective benefit to the public and all interested parties, including the licensee; and we can cite numerous instances of our own whereby effective regulation has fostered public acceptance and/or enhanced our extensive and successful efforts to protect our neighbors, our employees, the environment and the general public from the potential hazards of the materials with which we work.

Unfortunately, the Radiological Health Program has not been so productive. Rather, its acts and omissions, though perhaps well intended, have needlessly damaged us financially; have adversely impacted our radiation safety and environmental protection programs; and have caused us to devote an inordinate effort to allay irrational concerns that RHP has sought to arouse among our neighbors. We believe that these adversities arise from an enthusiasm for stringency on your part that is unwarranted by the facts; unauthorized by law; and contrary to the stated intent of authorizing legislation. Moreover, we are concerned that the Agency's draft is designed to authorize, rather than remedy such excesses. Specifically:

there are several instances where the Draft departs from 10CFR20 in ways which are more stringent without obvious cause, explanation or justification;

the draft omits a number of provisions that are available to NRC licensees, and which tend to mollify some of the excess stringencies inherent in the new NRC standards; and

finally, some sections of the draft authorize RHP to arbitrarily impose license conditions and other restrictions more stringent than authorized by law, and to restrain trade without fair cause or due process.

The following comments summarize the concerns that specific sections of the draft have aroused, and suggest the essential features of appropriate remedies.

The Power of the Agency to Take Escalated Enforcement Action and/or Impose Extra-Regulatory Requirements Must Be Limited

There is no evidence that the old NRC Regulations were too lax; and there is now a growing acknowledgement among radiation biologists that there is no truth to the notion that radiation is dangerous at low levels of exposure. Nevertheless, on the premise that the Linear No Threshold Model is valid, concerns have been aroused among the body politic, and the NRC has adopted more stringent regulations that you and we are obliged to respect.

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What we ask at this time is that the draft of appropriate sections of the proposed regulations be amended to provide:

that the Agency initiate no action to restrain trade in any way, or impose or continue any regulations or license conditions more stringent than required by NRC regulations without first documenting and furnishing to all effected licensee(s) an analysis which shows that such measures are required to protect public health and property; and

that before implementing any such action, the effected licensee be afforded an opportunity to contest the necessity for any such action before a neutral third party that is technically qualified to judge the merits of the dispute.

We are not suggesting here that the Agency forego its right to take all measures reasonably required to protect public health and property from the probable consequences of a real emergency. However, reasonable care must be exercised to protect licensees, their employees, neighbors and customers from the concern, cost and inconvenience of escalated enforcement action arising out of a declared emergency based upon the misvaluation of a minor incident or unsubstantiated rumor.

Our specific recommendations related to this issue, along with the justification therefor shall follow in due course under separate cover. Alternatively, we would be pleased to meet with you to discuss our concerns and proposed remedies if you wish. Meanwhile, our response would not be complete if we failed to note that we believe that Sections A.7, A.8, A.9, C.25, C.29, C.30, C.31, C.32, C.50(b), D.4, D101(c), D.206, D.301, D.502, D.1001(c), D.1008, D.109 and D.1010 may require major revisions.

Nuts and Bolts

Without any assurance that our specific comments are complete, we have analysed a substantial fraction of the proposed regulations; and our specific comments and suggestions for revisions are appended hereto as an Attachment.

Once again, we appreciate the opportunity to comment informally on your draft, and we trust that this letter and its attachment will help lead to a Notice of Proposed Rulemaking that will be a credit to your program and helpful to ours.

We have a vital interest in the cause of effective regulation; and we are available to assist the process in any reasonable way we can.

Very truly yours,

NEUTRON PRODUCTS, INC.

J.A. Ranshoff, President

Attachment

NEUTRON PRODUCTS inc

Attachment to Neutron Products' Letter Of January 11, 1995

The Draft does not incorporate the Controlled Area Concept

In revising 10CFR Part 20, the NRC introduced a Controlled Area concept that was not used in the old Part 20. §20.1003 defines Controlled Area as, "an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason." The NRC has written that their rationale for including Controlled Area in the revised Part 20 was "to provide regulatory recognition of the existence of such areas and to clarify their regulatory status." The NRC recognizes that to the extent a licensee has or will establish Controlled Areas, the ability to limit access to such areas provides an effective means of complying with the dose limit for members of the public. Therefore, the 2 mrem in any one hour rule need not apply in Controlled Areas. A Controlled Area, as used in Part 20, is not an Unrestricted Area, which is defined by §20.1003 as, "an area, access to which is neither limited nor controlled by the licensee." Both §20.1801 and §20.1802 use the language, "in a controlled or unrestricted area." Thus, a clear distinction is made between the two types of areas, and rules, such as §§20.1302(b)(2)(i) and (ii), which apply only to unrestricted areas, clearly should not apply to Controlled Areas.

Sections of Part 20 which now pertain or refer to, Controlled Areas are §20.1003, Definitions, "Member of the public" and "Public dose"; §20.1301(b), Doses for Individual Members of the Public; §20.1801, Security of Stored Material; §20.1802 Control of Material not in Storage and; §20.2104(a), Determination of Prior Occupational Dose.

In contrast to 10 CFR Part 20, the Agency in its draft has chosen not to include the Controlled Area concept. The draft makes no reference to Controlled Areas and does not define the term in either Secs. D.3 or A.2. The sections that correspond to §§20.1003, 20.1301(b), 20.1801, 20.1802, and 20.2104(a), i.e. Secs. A.2, D.301(c), D.801, D.802, and D.205 (a), respectively, have been rewritten by the Agency to exclude the term.

By eliminating the concept of Controlled Areas, the Agency has greatly enlarged the scope of Sec. D.301 (a)(i) as compared with §20.1301 (a)(2); although, the language is identical. While there remains some ambiguity, the 0.002 rem in any one hour limit appears to apply only to Unrestricted Areas, which as defined in Part 20 are not Controlled Areas. Thus, the Agency has broadened a restrictive limit upon licensees without showing a justifiable need to do so. In the answer to Question 106 the NRC has stated "the 2 mrem in an hour limit does not apply in a controlled area," this allows licensees to limit doses to Members of the Public in Controlled Areas by virtue of their being controlled, i.e., Members of the Public can be escorted, confined to low dose zones, or denied access. We feel the Agency should not seek to go beyond the measures established in Part 20 in the absence of compelling evidence that the NRC's policy in this matter represents a threat to public health.

The concept of, and special provisions, for Controlled Areas, separate from Restricted Areas, has potential value for licensees, regulators, and the public. The NRC has determined that where licensees have established such areas for various purposes and they provide ample protection for members of the public, the more stringent measures applied to Unrestricted Areas are not required. We recommend that the Agency return the concept of and provisions for Controlled Areas to the proposed Draft and suggest the following:

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Add to Sec A.2 the definition of "Controlled Area," as given in §20.1203, i.e., "Controlled Area" means an area, outside of a Restricted Area but inside the site boundary, access to which can be limited by the licensee for any reason."

Change the definition of "Member of the public" appearing in Sec. A.2 to that given by §20.1203, which reads, "'Member of the public' means an individual in a Controlled or Unrestricted Area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose."

Change the definition of "Public dose" appearing in Sec. A.2 to that given by §20.1203, which reads, "'Public dose' means the dose received by a member of the public from exposure to radiation and to radioactive material by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs."

"The licensee shall control and maintain constant surveillance of the licensed radioactive material that is in a controlled or unrestricted area and that is not in storage, or in a patient, or being transported or stored incidental to its transport by an authorized carrier."

Change Sec. D.205 to reflect recognition of Controlled Areas as in §20.2104(a), which begins, "For each individual who may enter the licensee's restricted or controlled area and is likely to receive, in a year, an occupation dose pursuant to Sec D.502, the licensee ..."

Members of the Public and Restricted Areas

10CFR 20.1003 defines "occupational dose" to mean, "the dose received by an individual *in a restricted area* or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person," whereas A.2 defines the same term as, "the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person." The NRC clearly means an individual entering restricted areas *for whatever reason* is not a Member of the Public which §20.1003 defines as, "an individual in a *controlled or unrestricted area*. However an individual is not a member of the public during any period in which the individual receives an occupational dose."

Furthermore, Public Dose is defined to mean "the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee ... either within the licensee's *controlled area or unrestricted areas*. It does not include occupational dose." In

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their answer to Question 33, the NRC responded, "Occupational dose limits apply to all individuals who enter a 'restricted area.' This is also the case under the old Part 20." The Agency's draft, beyond altering the two definitions at Sec A.2 to strike "controlled area" from each, rewords Sec D.301 (c) in a way that expressly contradicts the NRC and 10CFR Part 20 by substituting "restricted" for "controlled." Sec. D.301 (c), radically alters the scope and the intent of §20.1301(b), which is meant to provide a clear distinction between "restricted" and "controlled" areas, since §20.1003 defines "occupational dose" to mean, "the dose received by an individual *in a restricted area* or in the course of employment."

These changes are arbitrarily more restrictive than the federal regulation and create a possible conflict. Many questions are raised. When will an individual who is not an employee of the licensee be considered as a Member of the Public? What activities performed in a restricted area qualify such an individual as a worker?

Sec. A.2 defines worker as, "an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant." While this definition encompasses employees of the licensee, it may or may not be construed to include employees of contractors. Several categories of individuals with legitimate reasons for entering restricted areas who do not perform work directly for or under contract to a licensee and are not employed by a licensee of the State, the NRC, or another agreement state, might be considered as Members of the Public. They could include, for example, regulators conducting inspections and customers conducting quality assurance audits. It is conceivable that some of these individuals would make repeated entries to licensees' Restricted Areas throughout a calendar year and might receive significant exposure. Will the Agency compel licensees to limit the exposure of such individuals to 0.1 rem? This creates a possible conflict, especially in the case of agency or other government inspector whose authority to enter a restricted area cannot be limited by the licensee.

Entering a restricted area of a radioactive materials licensee is not a casual event; individuals who do so must be informed of the risks in so doing. The Agency's summary reversal of the NRC position places licensees in a regulatory "Catch-22", and will unduly hamper the conduct of normal and legitimate business activities. Without a compelling justification for the change and clearer language that eliminates the uncertainties and contradictions the change creates, we believe the Agency should allow the original intent of the NRC to stand. We strongly recommend that the Agency rewrite the proposed regulations by modifying the definitions of "public dose" and "member of the public" in Sec A.2 as noted above, and changing Sec D.301 (c) to read, "If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals."

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Planned Special Exposures

In revising Part 20, The NRC has made provision for Planned Special Exposures that allow up to 5 additional rem per year (25 rem lifetime) accounted for separately from routine occupational dose. The Planned Special Exposure provision was "designed to provide occupational dose flexibility similar to that provided by the previous 5(N-18) rule" under "very special circumstances" where "elimination of the 5(N-18) lifetime cumulative limit might create a severe handicap to the licensee's operation." §20.1206 specifies seven conditions that must be met for use of a PSE. §§20.2104, 20.2105, and 20.2204 impose additional requirements and Regulatory Guide 8.35 provides additional guidance regarding PSEs. Beyond the conditions of §20.1206, the draft adds in Sec. D.206 (a) the additional requirement to secure written permission from the Agency prior to the planned special exposure. This is not consistent with the NRC position and represents an unwarranted regulatory burden upon both the Agency and its licensees.

The conditions of §§20.1206, 20.2104, 20.2105, and 20.2204 are sufficient to protect the health and safety of workers engaged in planned special exposures. The requirement to secure Agency permission provides no additional protection and may be counterproductive. A Planned Special Exposure is by definition, "an infrequent exposure to radiation in an exceptional situation when alternatives that might avoid the higher exposures are unavailable or impractical." Given the Agency's history, the requirement to secure prior permission would likely amount to a practical negation of the provisions of §20.1206. Clearly, in providing for the Planned Special Exposure the NRC is allowing licensees to respond to extraordinary circumstances. Hypothetically, a planned special exposure might be justified in response to a deteriorating situation that if left uncorrected might develop into an emergency. Likewise, a highly skilled employee might accomplish in a PSE a nonroutine task which if assigned to other employees lacking this expertise would result in a much higher collective dose. In these cases and others the delay or possibility of delay would negatively affect radiation health and safety. One possible use of a PSE, specifically considered by the NRC, involves emergency nuclear surgery; does the Agency really wish to impede this kind of process?

It is the responsibility of the State to administer regulations that are consistent with the NRC, not to impose an additional layer of governmental management of licensee operations. The NRC has allowed its licensees the latitude to decide when a Planned Special Exposure is justified, and the provisions of §20.1206, etc. along with the threat of regulatory action if misused provide ample safeguards that Planned Special Exposures will be carefully planned and monitored. The burden of Sec. D.206 (a) will not provide additional safety and is likely to impair the usefulness of a Planned Special Exposure to provide additional safety for licensees and their employees. We recommend that the Agency follow the policy of the NRC in this matter and Sec D.206 (a) should be removed from the proposed rule.

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Dose Limits for Individual Members of the Public

In addition to the problems of Secs. D.301 (a)(ii) and (b) discussed above, the draft has gone beyond the original 10CFR Part 20 by eliminating two provisions contained therein. The draft eliminates the provision of §20.1301 (c) allowing licensees to apply for authorization to operate to a dose limit of 500 mrem for Members of the Public upon demonstrating need. The removal of this provision from the draft amounts to wholesale rejection of any possible future application without consideration of the merits.

Similarly, the provision under §20.1302 (c) allowing for adjustment of effluent concentration values in Appendix B to take into account actual physical and chemical characteristics of the effluents has been removed from the draft. Again this amounts to rejection before submission. Where the NRC has made some provision for adjusting the regulations to account for varying circumstances, the agency has not allowed for any discretion that would require competent technical evaluation on its part.

Rather than summarily reject possible applications of these provisions, the Agency should consider individual cases on their merits. We recommend that the provisions of §§20.1301 (c) and 20.1302 (c) be added to Secs. D.301 and D.302, respectively.

Surveys and Monitoring

In addressing the requirements for surveys, §20.1501 (a) (1) reads, "*May be necessary*," where Sec. D.501 (a)(i) reads, "*are necessary*." Similarly, where §20.1501 (a) (2) uses, "*Are reasonable* under the circumstances," D.501 (a)(ii) says, "*are necessary ...*" These changes in diction represent a trap for the licensee, who while making every effort to conduct "reasonable" surveys fails in some more unreasonable effort required *ex post facto* by the agency. In Secs. D.502 (a) and (b), as well as Sec. D.205 (a), the draft substitutes "who potentially may" for the "likely to" appearing in Part 20. The altered language will require licensees to waste valuable resources better applied to truly substantive radiological health and safety matters, on the trivial pursuit of even the most unlikely potentialities. We recommend the Agency adopt the original language of §§20.1501 (a)(1) and (2), 20.1502(a)(1) and (2) and 20.1502(b)(1) and (2) rather than seek to regulate licensees on matters that are both unreasonable and of low probable significance.

Under Sec. D.501 b, the draft adds to §20.1501 (b)'s requirement for periodic instrument qualification, "at intervals not to exceed 12 months." While annual calibration is appropriate for some equipment, other instruments should be calibrated more frequently and others are stable enough to require a less frequent schedule. It would seem advisable to rely on the experienced judgement of its licensees in this matter, offering appropriate technical guidance when necessary. Moreover, calibration of highly specialized equipment is often performed by skilled employees of outside organizations the scheduling of whom may not always accommodate a strict twelve month timetable. The insertion of the 12 month limitation

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appears to be a yardstick for the issuance of citations, rather than a credible regulation designed to protect workers and the public, therefore we recommend that Sec D.501 b be replaced with the original language of §20.1501 (b).

Sec D.501 d adds, "exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited." This provision has no equivalent in 10CFR Part 20, and raises a number of questions. What is the intended purpose of this additional requirement? Does it limit the use of fictitious individuals as part of a licensee's Quality Assurance measures for personnel dosimetry? Will MDE hold licensees legally accountable for the fraudulent activities of an employee? It is conceivable that the Agency sought to prevent licensees from fraudulently establishing evidence for exposures which were either never properly monitored or were originally determined to be in excess of regulatory limits. This would provide an understandable basis for the new rule; although, such action is already illegal under existing statutes. We feel that clarification by the Agency as to the purpose of this additional rule would be helpful and is required to avoid misinterpretation.

Control of Exposure from External Sources in Restricted Areas

10CFR 20.1601 (b) allows licensees to substitute "continuous direct or *electronic* surveillance that is capable of preventing unauthorized entry," to high radiation areas in lieu of controls required under §20.1601 (a). Sec D.601 (b) is more restrictive than §20.1601 (b), eliminating the provision for electronic surveillance and imposing an arbitrary time period of 30 days. Why has the agency chosen to eliminate the electronic surveillance option, and why has the 30 day time limit been imposed? If surveillance offers adequate protection against exposure for 30 days, it should be no less effective on the thirty-first day and thereafter. We feel the Agency's concern should be with the level of protection offered against exposure in high radiation areas not with the means used to achieve that control that should be left for the licensee's discretion when operating within the regulations. Automated electronic surveillance is just as effective as direct human surveillance, and possibly more so. Unless the Agency can offer justification for this change, we recommend that Sec. D.601 (b) be changed to read, "In place of the controls required by D.601 (a) for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry." This is consistent with §20.1601 (b).

10CFR 20.1602 requires that additional measures beyond §20.1601 to be taken to prevent access to very high radiation areas. No detail is given, but additional guidance is available from Regulatory Guide 8.38. The draft in Sec. D.602 substitutes this one paragraph rule with the provisions of §20.1603, which the NRC applies only to irradiators. The regulations covering irradiators are specifically tailored to the safety requirements of this type of equipment and are not appropriate nor readily applicable to other types of very high radiation areas. The NRC has made this clear in its response to Question 130. Where the NRC requires licensees to take adequate measures for these very high radiation areas, it leaves them substantial latitude to determine and implement appropriate controls; we believe the

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Agency has misapplied rules meant for specific cases to the general. We recommend that the Agency follow the form and language of 10CFR Part 20 in this matter and apply the rules under Sec. D.602 only to gamma irradiators, while applying the language of §20.1602 to all other very high radiation areas.

Environmental Report

In Sec. C.25 (b) the Agency seeks to impose a requirement on applicants for licenses or amendments to provide an environmental report, in addition to the information required by the application, if the agency determines their activity may significantly affect the quality of the environment. The determination of environmental impact and evaluation of an environmental report if necessary, would better fall under the province of some other regulatory body. For the agency to assert authority in this manner, creates an unfair imposition on byproducts licensees not required of other businesses within Maryland.

The regulations should sufficiently provide for the health and safety of workers and members of the public and protection of the environment. The Agency should not seek to expand upon the level of adequate protection in specific cases; to do so invites arbitrary and capricious abuse. Moreover, the provision within C.25 (b) which would deny a license should commencement of construction begin prior to the Agency having reached a conclusion is clearly outside the Agency's authority. If an Applicant wishes to commence construction, e.g., ground breaking, on speculation that a license will be forthcoming, it may be somewhat risky, but it is certainly within its legal right, providing all local regulations have been met. We recommend striking Sec. C.25 (b) in its entirety.

Waste Disposal

Section D.1001 differs substantially from §20.2001. Specifically, §§20.2001 (a)(2) and (3) which authorize waste disposal by decay in storage and release in effluents within limits are absent. These methods of waste disposal result in less exposure or potential for significant exposure to both workers and members of the public than other known alternatives. Yet the Agency would eliminate these methods in favor of transport to another facility involving more handling, employee exposure, financial cost, and potential for accidents during transportation. We recommend that, as a minimum Sec. D.1001 (a) be revised to include the provisions of §§20.2001 (a)(2) and (3).

Disposal by Release into Sanitary Sewerage

Section D.1003 (a)(i) prevents licensees from discharging licensed material into sanitary sewerage unless the material is readily soluble, or is a readily dispersible biological material,

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in water. Sewage generally contains complex organic solids with positive and negative surface charges from ionic chemical constituents. The charged surface sites are capable of binding soluble ionic species through an ion exchange mechanism. If a soluble, ionic, radioactive chemical is mixed with sewage containing fecal matter, a portion of the activity will reversibly bind to the solids in this manner. Whether soluble activity bound to fecal solids will be considered soluble, insoluble or as readily dispersible biological material remains unclear. The NRC has not provided guidance in this matter.

Since the majority of soluble activity disposed by licensee to sanitary sewerage consists of dilute aqueous solutions of ionic species and since in almost all cases the potential for ion exchange prior to and after leaving the facility exists, the impact of this issue is very serious. Unless this type of activity will be considered soluble or dispersible biological material and therefore acceptable for disposal under Sec. D.1003, a waste storage and handling crisis of immense proportions will occur. Licensees throughout Maryland will be compelled to store and alternatively treat and dispose of very large volumes of dilute low activity wastes; disposal to sanitary sewerage will all but cease to be an option. The Agency has an opportunity in publishing the proposed regulations to clarify the intent of Sec D.1003 (a)(i) as it pertains to bound activity; we recommend that it do so, and would be available to help draft specific language.

Depleted Uranium in Industrial Products and Devices

Section C.21 (e) provides for a general license for depleted uranium in industrial products and devices. Sec C.21 (e)(v) restricts the export of depleted uranium "except in accordance with a license issued by the U. S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110." In addition to providing for both general and specific licenses, 10 CFR Part 110 also provides exceptions in Section 110.1. Some devices have been exported under the exceptions rather than a license. Limiting exports in "accordance with license" appears to exclude these exceptions without any apparent justification. We doubt that it was MDE intention to restrict exports from Maryland that are allowable elsewhere. Adding the reference to 10 CFR 40.13 will make the draft compatible with the NRC regulations on "unimportant quantities" and clarify this issue. We recommend that Sec C.21 (e)(v) be changed to read:

- (v) shall not export such depleted uranium except in accordance with U. S. Nuclear Regulatory Commission regulations 10 CFR Part 110 or 10 CFR Part 40.13 "Unimportant Quantities."

Requirement for Sealed Source and Device Sheets

Section C.28 (n) reads, "Any applicant or specific licensee who wishes to manufacture and distribute a sealed source or device containing a sealed source shall provide sufficient information to complete a sealed source and device registration." Rather than making

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registration mandatory, it should be voluntary, and provision for the manufacture and distribution of "custom" sealed sources or devices should be retained. Making an application to the "source and device registration" voluntary allows distribution of sealed sources and devices containing sealed sources to licensees and others authorized to possess the specific sources and devices. For some custom designed sources and devices, the recipient prefers to obtain the authorization to possess from their regulatory agency (i.e., the U. S. Nuclear Regulatory Commission or another Agreement State) for economic or other reasons. For example:

it may be easier and less expensive for the recipient to obtain the necessary authorization to possess a custom designed and fabricated source or device for a specific purpose rather than for similar purposes by a number of recipients, which is the basis of the source and device catalog; or,

some recipients do not want (i.e., for proprietary reasons) the source or device manufacturer to know the details of the source application, without which it is difficult or impossible to support an application for "source and device registration."

some recipients cannot (i.e., for national defense reasons) tell the source or device manufacturer the details of the application or have the application in the public record as part of the "source and device registration."

In addition, the draft would prohibit the remanufacture and distribution of devices containing radioactive material that already have a "source and device registration" obtained by the original equipment manufacturer.

Since Neutron Products manufactures and sells custom designed cobalt-60 sources to licensees and government agencies who obtain approval for said sources from their own regulators, the draft Sec. C.28(n), if left uncorrected, would reduce Neutron Products' sales to authorized recipients and otherwise restrain trade without any justification. In addition, we question that the Agency has the authorization to regulate devices that may in the future, but do not currently, contain a sealed source. We therefore suggest that Sec C.28 (n) be changed to read:

"Any applicant or specific licensee who wishes to manufacture and distribute a sealed source or device containing a sealed source may provide sufficient information to complete a sealed source and device registration."

Control of Sources of Radiation Being Transported

By practice the United States Department of Transportation regulates the transportation of radioactive material. The U.S. DOT regulates common and private carriers and they are correspondingly exempt from the U. S. Nuclear Regulatory Agency regulations. With regard to

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Section D.802 (a) which reads, "The licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and that is not in storage or in a patient." It is our understanding that the definition of "storage area" set forth in Sec. E.3 applies to all properly packaged radioactive material while in transport or stored incidental to transport. Nevertheless, we feel that in the interest of clarity an appropriate definition of "storage" should be included in Sec. D.2 or Sec. D.802 (a) be changed to read:

"The licensee shall control and maintain constant surveillance of the licensed radioactive material that is in a controlled or unrestricted area and that is not in storage, or in a patient, or being transported or stored incidental to its transport by an authorized carrier."

Part T - Transportation of Radioactive Material

This part duplicates, often incorrectly, the regulations of the U. S. Nuclear Regulatory Commission and/or the U. S. Department of Transportation at 49CFR Subpart I. The Agency should not seek to separately regulate activities pertaining to interstate and international commerce. We believe the Agency should delete this part in its entirety or simply cite applicable federal regulation. However, if Part T is not deleted, the following sections, if effective, would cause Neutron Products major problems and should be corrected.

Previously Approved Type B Packages

Sec. T.8 (a)(2) restricts the use of Type B packages, not specifically designated as B(U) or B(M), and reads, "The package may not be used for a shipment to a location outside the United States after August 31, 1986, except as approved under special arrangement in accordance with 49 CFR 173.471."

Many countries permit the shipment of packages designated as B() and we recommend Sec.T.8 (a)(2) be changed to read:

"The package may not be used for a shipment to a location outside the United States after August 31, 1986, except as approved under special arrangement in accordance with 49 CFR 173.471, unless a special arrangement is not required by the recipient country or any intermediate country in which the package is transported."

Determination of Fabrication in Accordance with an Approved Design

Section T.14 (c) requires, "The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U. S. Nuclear Regulatory Commission," before first use. The design of many packagings used for international shipments are approved by Competent Authorities in other countries; and, it is normally not practical for a shipper to make the required determination by physical inspection of the packaging or the fabrication documents. We therefore recommend that Sec T.14(c) be changed to read:

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"The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U. S. Nuclear Regulatory Commission or appropriate Competent Authority. The determination need not be by physical inspection nor direct examination of the fabrication documents, but can be by acceptance of a certification by the owner or fabricator of the packaging."

External Radiation Levels

Section T.15 (i) reads, "External radiation levels around the packages and around the vehicle, if applicable; will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation. The transportation index shall not exceed ten." The phrase "and around the vehicle, if applicable," is confusing and does not seem to add anything. Furthermore Sec. T.15 (j) provides exceptions to (i). For the sake of greater clarity, we recommend T.15(j) read:

"External radiation levels around the packages will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation, except as provided in T.15(j)."