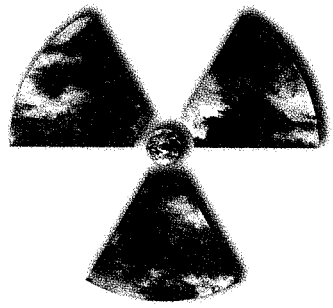
ICN Worldwide
Dosimetry Service



March 19, 2003

Secretary
U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
11545 Rockville Pike
Rockville, MD 20852

Subject: Proposed revision to 10 CFR Part 20 20.1501(c) and 10 CFR Part 20 20.1003

Dear Sir,

This letter and petition for rulemaking was also sent to Dr. William Travers.

I have been communicating recently with Dr. Sami Sherbini, of the Nuclear Regulatory Commission (NRC's) Office of Nuclear Material Safety and Safeguards and Mr. Roger Pederson from the Office of Nuclear Reactor Regulation regarding NRC's position on the use of electronic dosimetry to meet the requirements contained in 10 CFR Section 20.1201, "Occupational dose limits for adults,"and, the requirements with 10 CFR Section 20.1501(c), "General", with respect to standards to be followed to demonstrate compliance. I would appreciate written clarification from the NRC on this position given the following information as described below, and, request that the proposed revisions be considered for rulemaking.

In brief, I am recommending that any dosimeter used to report dose of record for DDE, SDE-WB, SDE-ME and LDE, demonstrating compliance with the dose limits specified in 10 CFR Section 20.1201, shall require personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology.

I am recommending the following revision to 10 CFR Section 20.1501(c):

Current 10 CFR Section 20.1501(c)
Subpart F—Surveys and Monitoring
10 CFR Section 20.1501 General.
(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with 10 CFR Section 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor—

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http://www.dosimetry.com e-mail: dosimetry@icnpharm.com
Toll Free: 800-251-3331 Worldwide: 1-714-545-0100 ext.6925 Fax: 1-714-668-3149

List of Attachments

Attachment 1 – Sander Perle Background

Attachment 2 - Primary reasons for revising 10 CFR Section 20.1003 and 10 CFR Part 20.1501(c)

Attachment 3 - Conference Report, Electronic Dosimetry Workshop, Gaithersburg, MD, October 14 – 16, 1998 - Journal of Research of the National Institute of Standards and Technology, Volume 103, No. 4, July – August 1998.

Attachment 4 - NRC POSITION ON THE USE OF ELECTRONIC DOSIMETERS (published approximately 1993)

Attachment 5 - Letter from Office of Nuclear Materials Safety and Safeguards – 1993 to Mr. Clyde E. Pearce, NC Systems, Inc.

Attachment 6 - Requiring NVLAP Accreditation of electronic dosimeters provides the following benefits

Attachment 7 - Conclusion

Attachment 1

Sander Perle Background:

I have been the Technical Director for ICN Worldwide Dosimetry Service since September 1996. We process approximately 5 million dosimeters annually (film, TLD and CR39). Prior to joining ICN, I was Supervisor Health Physics, Corporate Health Physics Department, Florida Power and Light Company, for 22 years. Prior to that, I was Supervisor Radiological Health Program, Florida Department of Health and Rehabilitative Services (Dade County, FL) for 4 years. I have an MS in Radiological Physics and BS in Chemistry and Biology. I am currently the Vice Chair, Health Physics Society Standards Committee (incoming Chair, July 2003), Chair, Health Physics Society Electronic Media Committee, and member NCRP Corporate Sponsor Development Committee. I have been a NVLAP Technical Expert since 1993, conducting on-site assessments for NVLAP, at accredited facilities, ensuring that they meet the requirements of ISO 17025, 10 CFR Part 20 15.285 and NIST Handbook 150. I have also received Total Quality Management and Statistical Quality Control training under the auspices of the Japanese Union of Scientists and Engineers (JUSE), during the attainment of the esteemed Japanese Deming Prize, awarded to Florida Power and Light Company in November 1989, (first company outside of Japan to ever be awarded the Deming Prize).

Attachment 2

The primary reasons I am proposing several revisions to 10 CFR Section 20.1003 and 10 CFR Part 20.1501(c) are as follows:

1. The NRC's written position is that although the NRC staff has "reservations" on the use of an electronic dosimeter as a "dose of record" due to technical and mechanical limitations, the current wording of 10 CFR Part 20 20.1501(c) precludes the testing and accreditation requirements for an electronic dosimeter (currently excludes "processed" dosimeters). The fact is that today's electronic dosimeters utilize multiple microprocessors that include many complex user input parameters that ultimately affect the final dose and/or dose rate reported. The dose determined from an electronic dosimeter is in fact, a "processed" dose. The electronic dosimeter requires that the licensee program the dosimeter to respond to various spectra, based on the calibration and other licensee set parameters. The NRC position is that since the current 10 CFR Part 20 20.1501(c) doesn't appear to include the definition of an electronic dosimeter, nothing prohibits a licensee from using an electronic dosimeter as a dose of record. The NRC philosophy is that the NRC on-site inspector can assess the validity of the electronic dosimeter quality assurance program. I submit that the NVLAP on-site assessor is the most appropriate individual to assess a facilities quality assurance program, and, to determine if the electronic dosimeter is capable of measuring and reporting accurate and precise dose results for workers in a specific radiation work environment, as they do for all other NVLAP accredited whole body dosimeters

2. The current wording of 10 CFR Part 20 20.1501(c) precludes the testing and accreditation requirements for an extremity dosimeter (finger or wrist dosimeter). In that 10 CFR Part 20 20.1201 Occupational dose limits for adults, specifies a dose limit, the annual limits to the extremities, which are a shallow dose equivalent of 50 rems (0.5 Sv) to the skin or to any extremity, it would seem logical that the dosimeter used to make this dose determination would be accredited through the same process as a whole body dosimeter.

3. NVLAP has for the past 8 years accredited extremity dosimeters per ANSI N13.32-1995, Performance Testing of Extremity Dosimeters. There is no reason to continue to exclude extremity dosimeters from requiring accreditation.

Proposed revision to 10 CFR Section 20.1501(c)
Subpart F—Surveys and Monitoring
10 CFR Section 20.1501 General.
(c) All personnel dosimeters used to determine the radiation dose and that are used by licensees to comply with 10 CFR Section 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license, must be processed and/or evaluated by a dosimetry processor.

I am recommending the following revision to 10 CFR Section 20.1003:

Current 10 CFR Section 20.1003
Individual monitoring devices (*individual monitoring equipment*) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and person ("lapel") air sampling devices.

Proposed revision to 10 CFR Section 20.1003

Individual monitoring devices (individual monitoring equipment) defined in 10 CFR Section 20.1003 Definitions, needs to be revised to mean devices designed to be worn by a single individual for the assessment of dose equivalent, used by licensees to comply with 10 CFR Section 20.1201, such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, electronic dosimeters, optically stimulated dosimeters and person ("lapel") air sampling devices.

I would be pleased to discuss my proposed revisions with you and your staff, at your convenience. I can be contacted by phone, 800 548-5100 x2306, e-mail at Sperle@icnpharm.com, or, US Postal Service.

I thank you for your attention to my request and look forward to a favorable response to my recommendations.

Sincerely,

Sander C. Perle
Director, Technical

cc: Betty Ann Torres, Program Manager
National Institute of Standards and Technology
100 Bureau Drive, Mail Stop 214
Gaithersburg, Maryland 20889-2140

Attachment 3

The NRC participated in an Electronic Dosimetry Workshop, documented in the following Conference Report, Electronic Dosimetry Workshop, Gaithersburg, MD, October 14 – 16, 1998 - Journal of Research of the National Institute of Standards and Technology, Volume 103, No. 4, July – August 1998.

The following summarizes the Conference Report, which concludes that electronic dosimeters need to be measured by the same standard as the passive dosimeters currently in use, and, defining the electronic dosimeter as processed dosimeters.

Conference Report Summary:

1. A search for consensus, among recommendations, and was intended to result in the broad acceptance of the electronic dosimeter for dose or record.

2. Ensure that the electronic dosimeter is measured by the same standard as the passive dosimeters currently in use.

3. This focused on defining the electronic dosimeter as a processed dosimeter in order to confirm that it fit the requirements of 10CFR20 for processed dosimeters.

4. It is clear that a process is used by the electronic dosimeter to change from radiation energy deposited in the detector to a dose quantity representing risk to the worker.

5. The user has an important role in routine testing and/or calibration of the electronic dosimeters and this may be the point at which quality control activities (accreditation) should be addressed.

Attachment 4

NRC POSITION ON THE USE OF ELECTRONIC DOSIMETERS (published approximately 1993):

The NRC published the following excerpt regarding electronic dosimeter and dose of record, approximate date 1993:

"NRC has stated that the use of electronic dosimeters as dosimetry of record is acceptable provided programs are established to ensure the reliability of the system and the accuracy of the data and that specific regulations do not prohibit their use (10 CFR 34.33 and 10 CFR 39.65). The elements of such a program include calibrations that are traceable to the National Institute of Standards and Technology (NIST), function checks before use, a comprehensive quality assurance program, administrative oversight to ensure the accuracy and security of the data, and specialized and highly trained personnel to operate and service the system."

Clarifying Comment: The NRC relies on the site inspector to validate the accuracy and precision of the electronic dosimeter, ensuring that the program meets all of the above quality assurance requirements. I submit that the NVLAP on-site assessor is the most appropriate individual to assess the overall electronic dosimeter quality program.

Attachment 5

Letter from Office of Nuclear Materials Safety and Safeguards – 1993 to Mr. Clyde E. Pearce, NC Systems, Inc.

The following are excerpts in a letter from Frederick C. Combs, Chief Operations Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards to Mr. Clyde Pearce, November 9, 1993 (full letter follows). Please note that Mr. Combs recognized that the NRC is aware of the potential problems involved in the use of electronic dosimeters as dosimeters of record, and, that the NRC is also proposing the development of a performance standard for electronic dosimeters comparable to that used in NVLAP:

1. This letter is in response to your inquiry to Dr. John Glenn, regarding use of electronic dosimeters for personnel monitoring. Your first question was whether the Nuclear Regulatory Commission will accept the electronic personnel dosimeter as a suitable replacement for film and thermoluminescent dosimeters (TLD).

2. The answer is in the affirmative: there is nothing in the regulations to preclude such use, with the exception of regulations that explicitly require the use of film or TLD.

3. You also enquired as to whether acceptance of the use of electronic dosimeters is contingent on the licensee's implementation of certain procedures. Acceptance is not contingent on any specific procedures to be implemented by the licensee.

4. The only requirement for use of electronic dosimeters is that the licensee follow the procedures and good practices normally observed when using radiation detection instruments to obtain important, safety-related measurements, such as proper maintenance and calibration, awareness of the instrument's limitations, training in its proper use, a good quality assurance program, accurate and secure data collection and storage, and so on. Licensees who choose to use electronic dosimeters must be prepared to implement such a program at their facilities.

5. In conclusion, we would like to note that the NRC is aware of the potential problems involved in the use of electronic dosimeters as dosimeters of record. However, it was concluded that electronic dosimeters could serve this purpose if the normal precautions mentioned above are observed.

6. Recognizing that there is no standard for electronic dosimeters comparable to that used in NVLAP accreditation, the NRC is developing a position paper outlining the appropriate practices and precautions to be observed when using electronic dosimeters. The NRC is also proposing the development of a performance standard for electronic dosimeters comparable to that used in NVLAP.

Clarifying Comment:

As far as a testing standard, NVLAP has been testing and conducting on-site assessments of facilities who voluntarily submit their electronic dosimeter for testing, as they do with their passive dosimeters, for approximately the past 10 years. In addition, ANSI N13.27-1992, Performance Specifications for Pocket-Sized Alarming Dosimeters/Ratemeters, has been in draft form since 1992. This standard, when issued, will specifically address the additional requirements that an electronic dosimeter shall meet, in addition to N13.11-20001, Criteria for Testing Personnel Dosimetry Performance. ANSI N42.20 addresses the type testing requirements for the electronic dosimeters. However, the fact that ANSI N13.27 has not been published or issued, does not detract from the proposed revision that requires all dosimeters, including electronic dosimeters, to undergo NVLAP blind proficiency testing, as do all other current passive dosimeters. In that the NRC has already stated the electronic dosimeter can be used, as a dose of record (with reservations), then requiring NVLAP accreditation, even without ANSI N13.27, does not change the fact that the NRC already recognizes the electronic dosimeter as dose of record. The NRC needs to initiate the actions it stated in the 1993 letter to Mr. Pearce, specifically, "The NRC is also proposing the development of a performance standard for electronic dosimeters comparable to that used in NVLAP."

November 9, 1993
Mr. Clyde E. Pearce
NC Systems, Inc.
5171 Eldorado Springs Drive
Boulder, Colorado 80303

Dear Mr. Pearce:

This letter is in response to your inquiry to Dr. John Glenn, regarding use of electronic dosimeters for personnel monitoring. Your first question was whether the Nuclear Regulatory Commission will accept the electronic personnel dosimeter (EPD) as a suitable replacement for film and thermoluminescent dosimeters (TLD). The answer is in the affirmative: there is nothing in the regulations to preclude such use, with the exception of regulations that explicitly require the use of film or TLD, such as 10 CFR Part 34, Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations, and 10 CFR Part 39, Licenses and Radiation Safety Requirements for Well Logging. As mentioned in the letter from NRC's Office of Nuclear Regulatory Research to Siemens on June 10, 1992 (see enclosure), licensees involved in radiography or well logging who wish to use EPDs may submit a petition for rulemaking to change these restrictions to permit use of EPDs.

You also enquired as to whether acceptance of the use of EPDs is contingent on the licensee's implementation of certain procedures. Acceptance is not contingent on any specific procedures to be implemented by the licensee. The only requirement for use of EPDs is that the licensee follow the procedures and good practices normally observed when using radiation detection instruments to obtain important, safety-related measurements, such as proper maintenance and calibration, awareness of the instrument's limitations, training in its proper use, a good quality assurance program, accurate and secure data collection and storage, and so on. Licensees who choose to use EPDs must be prepared to implement such a program at their facilities.

You also expressed concern that removal of the processor from the personnel dosimetry function removes third party involvement and therefore presents opportunities for altering the data. Although that possibility has always existed, we feel that it is the licensee's responsibility to ensure the security of the data. The methods used to attain the desired level of security would be reviewed within the context of NRC's licensing and inspection activities. It should also be pointed out that many NRC licensees, particularly nuclear power stations, receive NVLAP (National Voluntary Laboratory Accreditation Program) accreditation for their on-site dosimetry facilities and process their own dosimeters, thus eliminating third party involvement. No serious problems pertaining to data security have been encountered to date.

In conclusion, we would like to note that the NRC is aware of the potential problems involved in the use of EPDs as dosimeters of record. However, it was concluded that EPDs could serve this purpose if the normal precautions mentioned above are observed.

Recognizing that there is no standard for EPDs comparable to that used in NVLAP accreditation, the NRC is developing a position paper outlining the appropriate practices and precautions to be observed when using EPDs. The NRC is also proposing the development of a performance standard for EPDs comparable to that used in NVLAP.

We hope that we have addressed all your questions and concerns regarding use of EPDs, and we wish to thank you for bringing these concerns to our attention.

Sincerely,

(orig. signed by)
Frederick C. Combs, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

Attachment 6

Requiring NVLAP Accreditation of electronic dosimeters provides the following benefits:

Requiring NVLAP provides an unbiased third-party evaluation and recognition of performance, as well as expert technical guidance to upgrade laboratory performance. NVLAP accreditation signifies that a laboratory has demonstrated that it operates in accordance with NVLAP management and technical requirements pertaining to quality systems; personnel; accommodation and environment; test and calibration methods; equipment; measurement traceability; sampling; handling of test and calibration items; and test and calibration reports. NVLAP accreditation does not imply any guarantee (certification) of laboratory performance or test/calibration data; it is solely a finding of laboratory competence.

Attachment 7

Conclusion:

When an occupationally exposed worker wears a dosimeter, the worker expects that the dosimeter worn in fact will measure and report their dose, as accurately and precisely as technically feasible. This requires that the dosimeter is capable of performing adequately in the radiation environment that the worker is exposed to. Therefore, the dosimeter must be able to respond adequately in varying radiation environments; i.e., varying γ, β, x-ray and neutron fields, of varying dose rates and geometry's. Requiring NVLAP accreditation in 10 CFR Part 20 20.1501(c) assures the worker, the licensee, management and the NRC (as well as state regulators) that the dosimeter worn performs as expected. NVLAP accreditation requires both the testing to varying radiation types, energies, dose range and angularity, as well as an on-site assessment where the entire Quality System is assessed. While NVLAP accreditation does not give 100% assurance that the licensee is performing to the best of their ability, it does provide a degree of assurance that any serious programmatic deficiencies that exist are documented and NVLAP follow-up is initiated to ensure that these deficiencies are corrected. The most appropriate entity to assess a dosimetry program is a NVLAP technical expert, not a NRC on-site inspector.

The inspector can assess, review the NVLAP report, and then take appropriate actions to ensure that the licensee does comply with all requirements.

The worker deserves the best dose assessment possible. Without this proposed revision, there is no accredited testing performed for either extremity dosimeters or electronic dosimeters. There is no required on-site assessment by NVLAP. There is in fact, no standard that is required to be met. This does not serve the licensee well, and more importantly, leaves the workers with a dose that has no support from any recognized US or international standard. Our radiation workers deserve better. The NRC would be better prepared to stand behind a dose that is submitted as dose of record, and ultimately, the dose recorded would stand a better chance of being accepted in the event of litigation. Litigation and valid dosimetry drives the American Nuclear Insurers (ANI) to require any nuclear power plant worker who is expected to exceed 100 mrem in a calendar year, to wear two dosimeters (independent technology) to demonstrate that the dose of record can be substantiated using these varying technologies. The validity of the dose assigned logically requires that whatever dosimeter be used to meet 10 CFR Part 20 20.1201, it must meet recognized standards. The NRC has stated this in many venues, most notably the Electronic Dosimetry Workshop, documented in the following Conference Report, Electronic Dosimetry Workshop, Gaithersburg, MD, October 14 – 16, 1998 - Journal of Research of the National Institute of Standards and Technology, Volume 103, No. 4, July – August 1998. It is now time for the NRC to implement the necessary changes to 10 CFR Part 20 20.1501(c) that have been proposed for the past 10 to 15 years now.