

DELAWARE AUTHORITY ON RADIATION PROTECTION
SUMMARY OF MEETING
February 23, 2015
Harry Levin Center for Pharmacy History & Education
27 North Main Street
Smyrna, Delaware 19977

Members Present: (those with checks only)

R. Arm	√	W. Holden		M. Higgins	
F. Esposito	√	I. Turner	√	D. Tilton	√
L. Fox		T. May	√	R. Wier, Jr.	√
J. Dill	√	N. Melikechi		T. Hitchens	
F. Fisher-Tyler	√	K. Musto	√	G. Poirier	√

Guests:

R. Brinsfield	√	D. Parker		K. Shaughnessy	√
W. Fendt	√	D. Hill	√	J. Suder	√

F. Esposito, Authority Chairman, brought the meeting to order at 6:15 pm.

I. Agenda Adopted

F. Esposito proposed a change to the agenda by moving the regulatory review earlier, in the interests of having sufficient time for discussion and deliberation. I. Turner introduced a motion to accept the modified agenda, R. Wier, Jr. seconded and all voted to approve. The motion passed.

II. Authority Meeting Minutes

J. Dill introduced a motion to approve the November 3, 2014 Authority public meeting minutes, F. Esposito seconded and all voted to approve. The motion passed.

III. Chairman's Comments

F. Esposito expressed her sincere gratitude to the members of the Authority for coming out on such a cold winter night, for volunteering their time, and contributing to radiation safety for all Delawareans. She welcomed two new appointees to the Authority, including Gerald Poirier of the University of Delaware, and initiated introductions of all present. She asked F. Fisher-Tyler to provide any updates on committee activities. F. Fisher-Tyler replied that the committees do not have any upcoming actions, but the public education committee will hold a meeting or teleconference prior to the next Authority meeting, and will report out at that time.

IV. Informational Reports

F. Fisher-Tyler provided a summary of the ORC Activity Report, which included Authority efforts to procure supplementary resources for the Office of Radiation Control, status of the Authority Bylaws and Strategic Plan (both due for review in 2015), Authority committee activities, and a brief on ORC staff participation in radiologic emergency preparedness programs with the Delaware Emergency Management Agency (DEMA). She described efforts of the Authority to promote Department and Agency approval of travel for ORC staff to attend the Radiological Society of North America conference in Chicago, where all major x-ray manufacturers demonstrate their equipment, such as new models of CT scanners and radiation therapy units. She reported that two staff members were able to attend the conference in December, and attend many training courses that included hands-on opportunities. ORC staff also had opportunity to observe demonstration of a new model of radiation detection instrument that would represent a significant improvement in effectiveness and efficiency for the x-ray facility inspection program. She reported that Authority support for a critical reclassification of field radiation control positions into a career scientist ladder has progressed to an advanced stage, and it is anticipated that it will be resolved in March or April of 2015. F. Esposito, Authority Chairman initiated discussion of this critical reclassification request in 2013, for staffing sustainability of the program. F. Fisher-Tyler reported that F. Esposito has initiated a discussion with the Joint Finance Committee to obtain funding to replace ORC radiation detection instruments, which are dated and less reliable than is needed. F. Fisher-Tyler expressed her gratitude to the Authority leadership for working so diligently to assure that the ORC has the resources it needs to effectively carry out the radiation control regulations.

R. Brinsfield provided a summary of the ORC Monitoring Report of regulatory activities in 2014, including number of new x-ray rooms approved (37), number of facilities inspected (305), number of x-ray tubes inspected (967), number of violations issued (78), number of active radiation technologist & technician certificates issued (2942), certificates renewed (388), and new certificates issued (332). He reported that operational activity metrics increased across all categories from 2013 to 2014. F. Fisher-Tyler stated that the number of radiation technologist & technician certificates renewed each year will increase, with the certificate duration reduced from 4 years to 3 years in the regulation amended in May 2014. R. Arm observed there are a number of recurring types of violations noted, and asked whether outreach to professional societies might help to reduce that number. F. Fisher-Tyler stated that this suggestion would be placed on agenda for public education committee for consideration. F. Fisher-Tyler stated that inspectors hand out a pamphlet describing the resources available on the ORC webpage, and that Kelly Shaughnessy has also developed a very low cost magnet that both the ORC and Authority web links can be printed onto – so facility staff can have that handy in the office or clinical setting. F. Esposito remarked that is an excellent idea! J. Dill remarked the reports were excellent. F. Esposito remarked that the x-ray business in Delaware is booming, with growth in numbers of registered facilities and certified radiation technologists & technicians.

ACTION ITEM: Address public outreach to professional societies at next committee meeting, W. Holden & F. Fisher-Tyler.

V. Discussion Item - Phase 3 Regulatory Review

F. Esposito provided an overview of work carried out in 2014 by the Regulations Task Force, a committee of the Authority. She stated that it has taken several hours to get the proposed regulation into its current form, and thanked the task force she chaired for their contributions – namely, members W. Holden, I. Turner, W. Fendt, and F. Fisher-Tyler. She asked F. Fisher-Tyler to describe the process to be followed during this meeting, and indicated that the review would begin with Part D – Standards for Protection from Radiation. A hand-out was provided to all present, and the proposed rule document was also projected on a screen to guide the proceedings. F. Fisher-Tyler described the process, as follows.

OBJECTIVE:

- Review two chapters of regulations to address standards for protection against radiation, reconcile changes in regulatory oversight for radioactive materials, address notices, instructions and reports to workers, and make technical corrections, as needed.

DE Admin Code No.	Current DRCR and CRCPD SSR	Title
4465	Part D	Standards for Protection Against Radiation
4465	Part J	Notices, Instructions and Reports to Workers; Inspections

NEXT STEPS:

- The Authority and Agency will prepare, approve and publish a set of draft regulations for public comment (advanced notice of proposed rulemaking), per state procedure,
- The public will have a period to comment on the proposed rulemaking for 30 days, with public notice and opportunity to make comment verbally at a public hearing,
- The Authority and Agency will address public comments submitted, and incorporate changes into a final rule,
- The final rule will then be published, and posted to internet by the Registrar of Regulations,
- The Office of Radiation Control (ORC) will place a link to the final regulations on it's webpage and implement the final rule with the regulated community, on behalf of the Authority and Agency.

Comprehensive Title Page & Table of Contents

F. Fisher-Tyler asked for comments on the title page and table of contents, which have not been updated since the regulations had last been amended as a comprehensive set of 14 chapters in 2002.

R. Arm proposed that the effective dates for Phases 1 & 2 (June 10, 2013 and May 10, 2014) be added to the title page, to make it comprehensive.

I. Turner proposed adding notation to the Table of Contents reflecting that alphabetical part designations correspond to Suggested State Regulations published by the Conference of Radiation Control Program Directors (CRCPD, Inc.), a non-profit, non-governmental organization that includes Director Members from every state and territory in the United States. Suggested State Regulations (or SSR's) are developed by working groups of state & local radiation control program members, with review and concurrence by federal partner agencies prior to publication.

ACTION ITEM: Incorporate member comments into title page and table of contents for proposed rule, F. Fisher-Tyler

CLOSURE: Comments incorporated into proposed rule, 3/6/2015.

F. Fisher-Tyler worked quickly through the table of contents, pointing out the parts that had been amended in recent years (4465 Parts A, B, C, G, F, K, X), those under review in this phase (4465 Parts D & J) and those remaining to be reviewed (4465 Parts E, H, I & T), pending publication of newly revised Suggested State Regulations (SSRs) by the Conference of Radiation Control Program Directors (CRCPD, Inc.). F. Esposito reminded everyone that the Suggested State Regulations are developed by state and territorial radiation control program directors, are vetted by federal partners (NRC, FDA, CDC, etc.) and can be adapted to meet the needs of each state, with respect to state laws and regulatory processes. F. Fisher-Tyler stated that the page numbers would be reviewed after incorporating Authority comments into the proposed rule, to assure accuracy. R. Arm asked why there appear to be alphabetical parts missing.

ACTION ITEM: Insert a foot note in Table of Contents that explains the basis for the alphabetical parts, including statement that there are CRCPD SSR's that Delaware has decided not to adopt because they are not relevant to the state, for example Part M, Licensing Requirements for Land Disposal of Radioactive Wastes.

CLOSURE: Comments incorporated into proposed rule, 3/6/2015.

Part D – Standards for Protection Against Radiation

F. Fisher-Tyler stated that the content that is proposed for change are the body of Part D, and Appendix D (Sample Letter for Declaring Pregnancy). All other appendices are proposed to be retained in Part D, unchanged. F. Fisher-Tyler stated that an executive summary of changes will be prepared and distributed, once the Authority has approved a proposed rule for publication.

F. Fisher-Tyler reminded all that in the pre-decisional review with external stakeholders in November, definitions had been added to be more comprehensive and integrated with other parts amended in the previous two years, and that any definitions that exist in federal regulation (10 CFR 20, Nuclear Regulatory Commission) were kept identical, to maintain compatibility between the state and federal regulations.

R. Wier stated that the definitions of workers, someone engaged in work under a license or registration, or of employees. Who are the intended persons? F. Esposito indicated that her work as a radiologist for a hospital is covered by their state facility registration although she is not an employee of the hospital, and she is subject to these regulations.

F. Fisher-Tyler indicated that someone engaged in work could also include individuals managing the radioactive waste at a registered facility, or a visiting scientist or graduate student doing biomedical research through a research agreement, or students in a radiation technology program (radiologic technology or nuclear medicine) who are not actually employees of the registered facility (licensee or registrant). The person engaged in work under a license or registration is working with or in vicinity of a radiation source, regardless of their employment status.

R. Wier suggested that are implications in Part J with respect to how these definitions are applied. He referenced Part J, Section J.16, p. 5 – there is language about protections given to employees against discharge, discrimination. What are the protections, and who is subject to that? Is this intended to provide whistle-blower protection? He suggested that if intent is to provide protections to all workers (not just employee of facility licensee or registrant), then the language should be modified to reflect that directly. The sample letter for declaring pregnancy also raises questions with respect to protections. F. Esposito stated that the intent of the regulation is to provide protections to all individuals with potential exposure to radiation, so that includes employees but also others such as contractors, students, visiting scientists, etc. R. Wier stated that it should be stated clearly and directly that the protections are provided to all workers. So, if a dentist hires a dental hygienist who is an at will employee, is that person protected from retaliation as well as discharge or

discrimination under Part J, with respect to radiological working conditions under the regulation?

F. Fisher-Tyler indicated that the federal regulation 10 CFR Part 20 does not include definitions for employee or worker, however, it does include a definition of occupational dose. In Delaware Part D, "Occupational dose" means the dose received by an individual in the course of employment, education, or training in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received: from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with U.S. Nuclear Regulatory Commission Regulations, from voluntary participation in medical research programs, or as a member of the public.

R. Wier stated that the definition of employee or worker is important, and it is also important to be clear about what protections are provided to these individuals under Section J. 16. F. Fisher-Tyler agreed that this will be book-marked under the discussion of Part J later in the meeting agenda.

ACTION ITEM: In Part D, replace the word "employee" with "worker", evaluate definition for "worker",

CLOSURE: Comments incorporated into proposed rule, 3/6/2015.

F. Fisher-Tyler stated that there was an open action item from the last meeting regarding Section D.1201.c.II(2) referring to a multiplier of 0.30 when determining dose equivalent when two dosimeters are worn and reported dose exceeds 25 percent of the limit specified in D. 1201.a. After the meeting, it was determined that the Webster equation refers to a proposed dose equivalent determination when two dosimeters are worn, one worn at the collar outside a lead apron and one worn at the waist below the apron. E.W. Webster published the equation in the April 1989 *Health Physics Journal* (56[4]: 568-569), which is the basis for use of the 0.30 multiplier in CRCPD Suggested State Regulations, Section D.1201, Occupational Dose Limits for Adults. Accordingly, no changes were proposed for the referenced section of Part D above.

R. Wier asked what party the "licensee or registrant" is referring to in Section D.1206 – Planned Special Exposures. The section states that "A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in D. 1201 provided that each of the following conditions is satisfied (etc.). Section D.1206.b states that "the licensee or

registrant, and employer if the employer is not the licensee or registrant specifically authorizes the planned special exposure, in writing, before the exposure occurs.” It was confirmed that the regulatory requirement regarding planned special exposures is broadly construed to mean any individual who may receive an occupational dose in the course of employment, education or training, in which the individual’s assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person.”

Examples of such individuals who are not employees of the registrant or licensee, but whose assigned duties involve exposure to sources of radiation included radioactive waste disposal contractors, sealed source testers, shipping & receiving & security staff.

There was some discussion about Section D.1208 – Dose Equivalent to an Embryo/Fetus regarding dose equivalent for the duration of the pregnancy, and the circumstances for a worker to have the option to declare or undeclare a pregnancy. A sample letter for declaration of pregnancy was provided for in Appendix D of Part D. I. Turner provided some background regarding legal cases in the 1980’s that provided contributed to development of these kinds of declaration of pregnancy documents, to prevent discrimination for women of child-bearing potential performing hazardous work (ie. potential for chemical or radiation exposure). No changes were proposed as a result of this explanatory discussion.

There was some discussion about Section D.1903 – Exceptions to Posting Requirements regarding sections exempting rooms in hospitals where patients who had been administered radioactive materials may be present. The task force deliberated on this section, and based on the U.S. Nuclear Regulatory Commission being primary regulator of radioactive material used for medical purposes (10 CFR Part 35: Medical Use of By-Product Material), these exemption statements were removed. No changes were proposed as a result of this discussion.

There was some discussion about Section D.2105 – Records of Planned Special Exposures, regarding whether the Agency has capacity to accept transfer of dosimetry records should a company go bankrupt or otherwise out of business. I. Turner asked how the Agency would handle those records, F. Fisher-Tyler replied that such records would be scanned and stored electronically, consistent with state procedure for radiation control registration or licenses. No changes were proposed as a result of this discussion.

It was determined that all references in Part D to Agency Form X, Y or Z need to be identified as “Part J, Appendix A, B or C.”

It was determined that there were a few page number errors to be corrected.

ACTION ITEM: **Modify references to Agency Forms X, Y, Z to being in Part J, Appendix A, B or C, Correct page numbers.**

CLOSURE: **Comments incorporated into proposed rule, 3/6/2015.**

There was some discussion regarding Part D, Appendix D – Sample Letter for Declaring Pregnancy. Reference to the radiation control regulations was identified as needing updating to Delaware Administrative Code 4465. There was a question about circumstances when a pregnancy might be un-declared, W. Fendt indicated that an individual working in a radiation job could un-declare a pregnancy when they are no longer interested in being afforded protection with respect to limiting radiation dose to the embryo/fetus.

There was some question about whether individuals are provided this information when they start a job with radiation exposure. I. Turner indicated that this is included in orientation for new employees, and if they declare a pregnancy, they are monitored more closely to ensure radiation dose limit to embryo/fetus is not exceeded.

There was some concern expressed about the confidentiality of the declaration letter, once completed by the individual. Suggestion was made to provide language in the header identifying this letter as being confidential health information.

ACTION ITEM: **Modify header of Appendix D – Sample Letter for Declaring Pregnancy to reflect Confidential Health Information.**

CLOSURE: **Comments incorporated into proposed rule, 3/6/2015.**

There was discussion about Section J.1 – Purpose and Scope regarding applicability to all workers, and it was agreed to modify language to reflect individuals engaged in activities under a license or registration.

ACTION ITEM: **Modify Section J.1 purpose & scope section to reflect individuals *including but not limited to employees*, and Modify Section D.1003 – Definitions to reflect individuals *including but not limited to employees*.**

CLOSURE: **Comments incorporated into proposed rule, 3/6/2015.**

There was discussion about Section J.16.c – Requests by Workers for Inspections, regarding discrimination vs. retaliation. R. Wier suggested replacing “discriminate” with “retaliate”.

ACTION ITEM: **Make edit to replace “discrimination” with “retaliate.”**

CLOSURE: **Comments incorporated into proposed rule, 3/6/2015.**

There was some discussion about Section J.17 – Inspections Not Warranted; Review regarding whether there should be an opportunity for an appeal. J. Suder stated that there are complaint investigations in public health regulations that do have appeal language, and she volunteered to provide that language for this section.

ACTION ITEM: Insert appeal language consistent with public health law.
CLOSURE: Comments incorporated into proposed rule, 3/6/2015.

Appendices A, B & C were reviewed, and edits identified to address discussion about terminology referring to “employer, employees and employment”, and general agreement to replace “employer with the registrant”, employee with worker, and employment with work,” throughout each appendix.

ACTION ITEM: Amend language to reflect terminology changes discussed.
CLOSURE: Comments incorporated into proposed rule, 3/6/2015.

F. Esposito introduced a motion to conditionally approve Part D and Part J, with edits identified during this meeting to be incorporated into the proposed rule by the Office of Radiation Control. I. Turner seconded the motion, and all voted to approve. The motion passed.

V. Old Business

No old business to report.

VI. New Business

Review of Strategic Plan and Bylaws tabled until next meeting.

VII. Public Comments

There were no public comments.

VIII. Adjournment

I. Turner introduced a motion to adjourn. K. Musto seconded and all voted approve. The motion passed. The Authority meeting adjourned at 8:15 pm.

The next meeting of the Authority is scheduled for May 4, 2015 at 6 pm, at the Harry Levin Center for Pharmacy History & Education in Smyrna, Delaware.

Respectfully submitted,

Frieda Fisher-Tyler, MHS, CIH
Administrative Agent,

Authority on Radiation Protection
Radiation Control Program Director
Delaware Division of Public Health