PUBLIC PACKET

OREGON BOARD OF DENTISTRY

BOARD MEETING
DECEMBER 14, 2012

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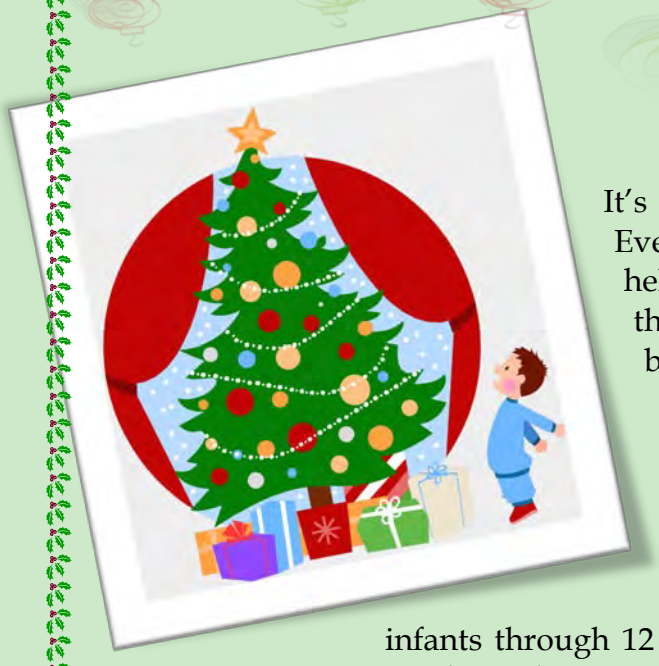
29th Annual State Agency Toy Drive!



It's once again time for the Annual State Toy Drive! Every year all state agencies have the opportunity to help make the Holidays 'Happy' for needy children throughout the State and this year seems like it may be an especially hard one for many families.

If you would like to participate, please bring a new, unwrapped present of your choice with you to the December 14th Board Meeting. A box will be available in the OBD lobby for any donation you wish to make. Items are needed for infants through 12 years. Please don't think you have to limit your items to toys either, educational items as well as clothing are happily accepted.

If you don't have time to go shopping but would still like to contribute, you can write a check payable to "The Salvation Army". Any funds donated will be used to purchase toys that go directly to the Salvation Army's 'Toy for Joy' Program. Receipts will be available upon request.

If you have any questions feel free to give me a call!

Thanks!

Lisa Warwick
Office Specialist
Oregon Board of Dentistry

A few important requests:

- Please do not wrap the gifts.
- Videos must be rated "**G**".
- Gifts for ages 0 through 12 years old are needed.
- ***No toy guns!***
- Please remember to include batteries when donating a battery-operated gift.
- Rather than purchase one very expensive gift, purchase several less expensive gifts.
- Suggested price range for each gift is $5-$20.

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APPROVAL OF MINUTES

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OREGON BOARD OF DENTISTRY
MINUTES
October 5, 2012

MEMBERS PRESENT:	Patricia Parker, D.M.D., President Jonna E. Hongo, D.M.D., Vice-President Brandon Schwindt, D.M.D. Alton Harvey, Sr. Julie Ann Smith, D.D.S., M.D. Darren Huddleston, D.M.D. Jill Mason, M.P.H., R.D.H. Norman Magnuson, D.D.S. Mary Davidson, M.P.H., R.D.H.
STAFF PRESENT:	Patrick D. Braatz, Executive Director Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator Daryll Ross, Investigator (portion of meeting) Harvey Wayson, Investigator (portion of meeting) Michelle Lawrence, D.M.D., Consultant (portion of meeting) Rodney Nichols, D.D.S., Consultant (portion of meeting) Lisa Warwick, Office Specialist (portion of meeting) Stephen Prisby, Office Manager (portion of meeting)
ALSO PRESENT:	Lori Lindley, Sr. Assistant Attorney General
VISITORS PRESENT:	Sheri Billetter, ODAA; Beryl Fletcher, ODA; Dana Shipley, R.D.H., ODHA; Lisa Rowley, R.D.H., Pacific University; Judd Larson, D.D.S., ODA; Bill Saiget, D.D.S., Interdent; Patricia Peirano Franklin, Pediatric Dentist; Steven E. Timm, D.M.D., ODA; Pamela Lynch, R.D.H., ODHA

Call to Order: The meeting was called to order by the President at 7:30 a.m. at the Board office; 1600 SW 4th Ave., Suite 770, Portland, Oregon.

NEW BUSINESS

MINUTES
Dr. Magnuson moved and Ms. Mason seconded that the minutes of the August 3, 2012 Board meeting be approved as amended. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

ASSOCIATION REPORTS

Oregon Dental Association
Dr. Larson stated that the Oregon Mission of Mercy saw over 1200 patients and provided $750,000 worth of dental work. He also took the opportunity to introduce Dr. Steven Timm as the new ODA Vice-President.

Oregon Dental Hygienists' Association
Ms. Shipley invited everyone to the ODHA's Fall Dental Health Conference, being held October 26 - 28. She also thanked Teresa Haynes and Paul Kleinstub for presenting at the conference in advance.

Oregon Dental Assistants Association
Sheri Billetter stated that the ODAA will be having their association meeting as part of the ODHA's Fall Dental Health Conference on Oct. 27th and added that Ms. Fletcher of the ODA will be presenting at the meeting on the topic of best management practices and how they impact staff.

COMMITTEE AND LIAISON REPORTS

WREB Liaison Report
Dr. Magnuson stated that there will be a strategic planning meeting in November and that the minutes from the last Board meeting were in the Board handout.

AADB Liaison Report
Dr. Parker stated that the ADA and AADB meetings would be occurring soon and that there will be a full report at the December Board meeting. Mr. Braatz stated that there will be a discussion regarding Botulinum toxin type A at the meeting. He stated that there is a 50 page report, which would be made available to the Board shortly, with the most current state standings on the matter.

ADEX Liaison Report
Dr. Parker had nothing new to report and that the next ADEX meeting would take place in November.

NERB
Dr. Hongo had nothing to report.

Licensing, Standards and Competency Committee Meeting Report
Dr. Magnuson stated that the Licensing, Standards and Competency Committee meeting was rather long and that ultimately the committee decided that general dentists with appropriate training, were within their scope of practice to be allowed to use Botulinum toxin type A with dental justification. He stated that a motion was made and passed to send this to the Rules Oversight Committee for development of more specific rules. Dr. Schwindt clarified with Dr. Magnuson that dermal fillers were not part of the Botulinum toxin type A decision. Dr. Magnuson also stated that the Committee had decided to leave the current CE requirements as they were.

Committee Meeting Dates
Mr. Braatz stated that he and Dr. Schwindt were working on planning a Rules Oversight Committee meeting and that more information would be available soon.

EXECUTIVE DIRECTOR'S REPORT

Budget Status Report
Mr. Braatz stated that the budget was performing as expected and that he's been watching it closely due to the current economy. He added that the latest budget report for the 2011-2013 Biennium was attached and that the report, which is from July 1, 2011 through August 31, 2012, shows revenue of $1,544,653.39 and expenditures of $1,307,398.42. Revenues continue to be on target and the expenditures are actually below what was budgeted.

OBD 2013-2015 Agency Budget Request
Mr. Braatz stated that he included a copy of the 2013-2015 Agency Budget Request for the Board's review. He added that the Budget has been submitted to the Department of Administrative Services and he has not yet received a response from them.

Customer Service Survey Report
Mr. Braatz attached a chart which shows the OBD State Legislatively Mandated Customer Service Survey Results from July 1, 2012 through August 31, 2012. The results of the survey show that the OBD continues to receive positive comments from the majority of those that return the surveys. The booklet containing the written comments that are on the survey forms, which staff has reviewed, are available on the table for Board members to review. Mr. Braatz reported that the staff was currently receiving an 80% positive response from those surveys that are being returned to us.

Board and Staff Speaking Engagements
Friday, September 7th - Mr. Braatz made a presentation to the Oregon House of Delegates in Redmond, Oregon.

HPSP Annual Report
Mr. Braatz attached the 2nd Annual HPSP report for the Board to review. He stated that the bill for the HPSP program was $200,000.00 for just this past year and that he's not sure what it will be next year. He added that he felt there would be some changes to this program in the upcoming year due to feedback from the various boards that have been required to use this program.

Agency Head Financial Transaction Report 7/1/2011-6/30/2012
Mr. Braatz presented the Agency Head Financial Transaction Report showing all his leave, Spots Card purchases, travel reimbursements and other various expenditures for the Board's review. Dr. Huddleston moved and Ms. Davidson seconded that the Board approve the Agency Head Financial Transaction Report as presented. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

Legislative Report on the Reimbursement of Expanded Practice Permit Dental Hygienists
Mr. Braatz stated that the Board could find their first report on the Reimbursement of Expanded Practice Permit Dental Hygienists in their books. He stated that this report covers the period from January 1, 2012 to June 30, 2012 and that the next report will have a full two years of data for the Board to review.

Newsletter
Mr. Braatz stated that he was still attempting to get the newsletter out for late Fall of 2012.

Board Resignation
Mr. Braatz stated that Mr. David Smyth has officially resigned from the Board. His term officially ended last March, yet Mr. Smyth continued in his position as public member with the Board in hopes that the Governor's Office would be able to fill the position quickly. Mr. Braatz stated that it appears that this was not the case. Mr. Smyth had personal issues to attend to and felt it was time to officially resign the seat.

Staff Return
Mr. Braatz stated that Mr. Daryll Ross has returned to work and we are all happy to have him back.

UNFINISHED BUSINESS

CORRESPONDENCE

The Board received a letter from John L. Krump, D.D.S.
Dr. Krump sent a letter to the Board asking them to consider a rule change regarding patient records for individuals who have received dental implants. Ms. Mason moved and Dr. Magnuson seconded that this be moved to the Rules Committee for establishment of rules as this is currently an issue for dentists. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

The Board received a letter from Louis Malcmacher, D.D.S., M.A.G.D.
Dr. Malcmacher sent a letter to the Board, as well as several articles, in an attempt to show the Board that Botox and dermal fillers are well within the scope of the practice of Dentistry.

The Board received a letter from Samuel A. Fleishman, M.D.
Dr. Fleishman sent a letter to the Board asking for their professional opinion regarding the scope of Dentistry as it pertains to dentists and some recent advertising claims that dentists are within their scope of practice to diagnose sleep apnea by utilizing home sleep tests. The Board directed Mr. Braatz to respond with a letter stating that, "The ordering, interpreting and managing of tests for sleep apnea is outside the scope of dentistry, whereas making the appliance is well within the scope of dentistry."

OTHER BUSINESS

Articles and News of Interest (no action necessary)
☐ Nothing Presented

EXECUTIVE SESSION: The Board entered into Executive Session pursuant to ORS 192.606 (1)(f), (h) and (k); ORS 676.165; ORS 676.175 (1), and ORS 679.320 to review records exempt from public disclosure, to review confidential investigatory materials and investigatory information, and to consult with counsel.

PERSONAL APPEARANCES AND COMPLIANCE ISSUES
Licensees appeared pursuant to their Consent Orders in case numbers **2007-0071** and **2005-0117.**

LICENSING ISSUES

OPEN SESSION: The Board returned to Open Session.

CONSENT AGENDA

2013-0033, 2013-0016, 2013-0024, 2013-0037, 2013-0036, 2013-0017, 2013-0045 and **2013-0012** Dr. Hongo moved and Mr. Alton seconded that the above referenced cases be closed with No Further Action or No Violation of the Dental Practice Act per the staff recommendations. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

COMPLETED CASES

2011-0169, 2012-0196, 2012-0129, 2010-0114, 2011-0171, 2013-0009, 2011-0223, 2012-0065, 2011-0232, 2010-0094, 2012-0067, 2012-0191, 2013-0013, 2013-0010, 2013-0040 and **2012-0141** Dr. Hongo moved and Dr. Magnuson seconded that the above referenced cases be closed with a finding of No Violation of the Dental Practice Act or No Further Action per the Board recommendations. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Smith recused herself on case # 2013-0009 and case # 2013-0010. Dr. Schwindt recused himself on Case # 2012-0065.

ALLEMAN, ALFRED D., D.M.D. 2012-0026

Mr. Harvey moved and Ms. Mason seconded that the Board issue a Notice of Proposed Disciplinary Action and offer the Licensee a Consent Order in which the Licensee would agree to make a restitution payment in the amount of $4,659.00 to the patient. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason and Dr. Magnuson voting aye. Ms. Davidson recused herself.

2012-0054

Dr. Huddleston moved and Dr. Magnuson seconded that the Board close the matter with a STRONGLY worded Letter of Concern addressing the issue of ensuring that when informed consent is obtained prior to providing treatment, PARQ or its equivalent is documented in the patient records and that a dental diagnosis is also documented in the patient's records prior to providing treatment. The motion passed with Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Hongo recused herself.

DAVENPORT, RICHARD W., D.M.D. 2011-0059

Dr. Schwindt moved and Ms. Davidson seconded that the Board issue a Notice of Proposed Disciplinary Action and offer the Licensee a Consent Order in which the Licensee would agree to be reprimanded and make a restitution payment to the patient in the amount of $6,600.00. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

GRUBBS, HEIDI J., R.D.H. 2011-0044

Ms. Mason moved and Dr. Smith seconded that the Board issue a Board Order requiring Licensee to undergo a substance use disorder evaluation at a Board approved facility within 30 days of the effective date of the Order, unless the Board grants an extension and informs Licensee in writing. Licensee shall provide the Board with the evaluation reports within seven days of receipt. The evaluation(s) are to be at the Licensee's expense. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

LEE, CHRIS Y.J., D.M.D. 2012-0010

Dr. Smith moved and Dr. Hongo seconded that the Board issue a Notice of Proposed Disciplinary

Action and offer the Licensee a Consent Order in which the Licensee would agree to be reprimanded, to complete at least three hours of continuing education in record keeping within six months and cease placing dental implants pending further order of the Board. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

2010-0139
Dr. Magnuson moved and Dr. Hongo seconded that the Board close the matter with a Letter of Concern addressing the issue of ensuring that informed consent is obtained prior to providing treatment, PARQ or its equivalent is documented in the patient records and that the patient has a clear understanding of the proposed outcome of treatment. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

REGAN, MICHAEL C., D.M.D. 2010-0186
Ms. Davidson moved and Dr. Hongo seconded that the Board issue a Notice of Proposed Disciplinary Action and offer the Licensee a Consent Order incorporating a reprimand, a $5,000 civil penalty, to complete three hours of continuing education in record keeping which must be completed within six months of the effective date of the Order and to cease implant placement until successful completion of the Board's mentoring program with a focus on implant placement. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

2012-0131
Mr. Harvey moved and Dr. Huddleston seconded that the Board close the matter with a Letter of Concern reminding the Licensee that the patient record must include the date, name of, quantity of, and strength of all drugs dispensed, administered or prescribed and a diagnosis that supports the use of such medications. The motion passed with Dr. Hongo, Mr. Harvey, Dr. Huddleston, Dr. Smith, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Schwindt recused himself.

2011-0204
Dr. Huddleston moved and Dr. Hongo seconded that the Board close the matter with a Letter of Concern addressing the issue of ensuring that the Licensee be in compliance with the requirements for maintaining the Licensee's Nitrous Oxide Permit. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

PREVIOUS CASES REQUIRING BOARD ACTION

COMBE, R. OWEN, D.M.D. 2005-0117
Dr. Schwindt moved and Dr. Smith seconded that the Board deny Licensee's request to have a DEA registration. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

FRYE, RAYMOND L., D.M.D. 2012-0064 and 2012-0117
Dr. Smith moved and Mr. Harvey seconded that the Board accept Licensee's offer of a Consent Order incorporating a reprimand, pay a $10,000 civil penalty and complete three hours of continuing education in record keeping within six months. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

GARCIA, PETER, D.M.D. and GARCIA, ARLENE, R.D.H. 2012-0150
Ms. Mason moved and Ms. Davidson seconded that the Board accept Licensees' proposal and offer each respondent an individual Consent Order incorporating a reprimand and 50 hours of Board approved pro bono community service within 18 months, per Board protocol. The motion passed with Dr. Schwindt, Mr. Harvey, Dr. Smith, Ms. Mason, Dr. Huddleston, Dr. Magnuson and Ms. Davidson voting aye. Dr. Hongo recused herself.

GARVIN, JACK G., D.M.D. 2011-0090
Dr. Magnuson moved and Dr. Smith seconded that the Board deny Licensee's request and require him to retire his Oregon dental license effective 10/5/12. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

LOXLEY, EMINE C., D.M.D. 2011-0078
Ms. Davidson moved and Dr. Hongo seconded that the Board deny Licensee's offer to resolve the matter, to issue a Third Amended Notice of Proposed Disciplinary Action, offer Licensee a Consent Order incorporating a reprimand and pay a $2,000 civil penalty. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

PILCHER, JAMES C., D.D.S. 2011-0013
Mr. Harvey moved and Dr. Hongo seconded that the Board accept Licensee's dental license resignation in lieu of further action for his failure to follow a Board order. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Huddleston recused himself.

RODRIGUEZ, ROBERT L., D.M.D. 2009-0275
Dr. Huddleston moved and Mr. Harvey seconded that the Board deny Licensee's request to resolve the matter with a Letter of Concern and affirm the Board's action of 2/10/12 and require that the continuing education requirement be completed within six months. The motion passed with Dr. Hongo, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Schwindt recused himself.

SMITH, LYNN E., D.M.D. 2010-0079
Dr. Schwindt moved and Dr. Hongo seconded that the Board offer Licensee an Amended Consent Order by which Licensee is released from the requirement to submit to an assessment for competency in the D-PREP program, as per his Consent Order, dated 6/17/11, providing he agrees to enter into the Board's mentoring program. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

LICENSURE AND EXAMINATION

Review of Request for General Anesthesia Permit
Dr. Smith brought the General Anesthesia Application of Licensee M.E. to the Board for review pursuant to OAR 818-026-0030(e). Dr. Schwindt moved and Ms. Mason seconded that Licensee M.E.'s request for a General Anesthesia Permit be granted. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Smith recused herself.

Review of Request for Minimal Sedation Permit

Dr. Smith brought the Minimal Sedation Application of Licensee R.M. to the Board for review pursuant to 818-026-0030(e). Dr. Magnuson moved and Ms. Mason seconded that Licensee R.M.'s request for Minimal Anesthesia Permit be granted. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye. Dr. Smith recused herself.

Soft Reline Instructor Permit

Dr. Huddleston moved and Ms. Mason seconded to grant Ms. Dean a Soft Reline Instructor Permit. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

Ratification of Licenses Issued

Ms. Davidson moved and Dr. Magnuson seconded that licenses issued be ratified as published. The motion passed with Dr. Hongo, Dr. Schwindt, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

Dental Hygiene

H6262	SARAH ANN GEARK, R.D.H.	7/24/2012
H6263	NICOLE LEIGH OLTS, R.D.H.	7/24/2012
H6264	KAYLA R SOTO, R.D.H.	7/24/2012
H6265	KELLY J JORDAN, R.D.H.	7/24/2012
H6266	TANIA COSTEA, R.D.H.	7/24/2012
H6267	MEREDITH LYNN ROBINSON, R.D.H.	7/24/2012
H6268	ASHLY T BARBER, R.D.H.	7/24/2012
H6269	BRITTANY BURCHATZ, R.D.H.	7/24/2012
H6270	KRISTIN L SHOEMAKER, R.D.H.	7/31/2012
H6271	BENJAMIN O SANDVICK, R.D.H.	7/31/2012
H6272	JESSICA L ROTH, R.D.H.	7/31/2012
H6273	CELESTE L PETERSON, R.D.H.	7/31/2012
H6274	MAAROF T SADIQ, R.D.H.	7/31/2012
H6275	KENDRA MICHELLE PURDY, R.D.H.	7/31/2012
H6276	REBECCA ANN BAILEY, R.D.H.	7/31/2012
H6277	MEGAN L JOHNSON, R.D.H.	7/31/2012
H6278	AMBER DAWN NICHOL, R.D.H.	7/31/2012
H6279	ASH L EDWARDS, R.D.H.	7/31/2012
H6280	ANGELA G KREMER, R.D.H.	7/31/2012
H6281	NICOLE LYNN CHAKARUN, R.D.H.	8/3/2012
H6282	MIJUNG UNVERSAGT, R.D.H.	8/3/2012
H6283	STACEY WILTERMOOD, R.D.H.	8/3/2012
H6284	NATASHA X BOYCE, R.D.H.	8/3/2012
H6285	MARIE WOURMS, R.D.H.	8/3/2012
H6286	KAWINTHRA P LUCK, R.D.H.	8/3/2012
H6287	SHELLYANN M GIBSON, R.D.H.	8/3/2012
H6288	NICOLE HURD, R.D.H.	8/3/2012
H6289	JESSICA A THOMAS, R.D.H.	8/3/2012
H6290	DESIREE A DUBISAR, R.D.H.	8/3/2012
H6291	ANNIE M HOUSTON, R.D.H.	8/3/2012

H6292	HEATHER A BESSE, R.D.H.	8/3/2012
H6293	KRISTINE SUE JENNINGS, R.D.H.	8/2/2012
H6294	RACHAEL E CURTIS, R.D.H.	8/6/2012
H6295	ALLISON M RAPHAEL, R.D.H.	8/10/2012
H6296	LAUREN A LAWLESS, R.D.H.	8/10/2012
H6297	KYLE A DENMARK, R.D.H.	8/10/2012
H6298	RENEE MORTIMORE, R.D.H.	8/10/2012
H6299	ALLISON M ALEKSIC, R.D.H.	8/10/2012
H6300	KAILI M RUTKOWSKI, R.D.H.	8/10/2012
H6301	ASHLEY M MCCLURE, R.D.H.	8/10/2012
H6302	KATHERINE ANN LIERMANN, R.D.H.	8/10/2012
H6303	CHRISTINE M BRENNAN, R.D.H.	8/16/2012
H6304	MICHELLE A VAUGHN, R.D.H.	8/16/2012
H6305	KATARZYNA TEEGARDEN, R.D.H.	8/16/2012
H6306	LE TRAN, R.D.H.	8/16/2012
H6307	INNA ANATOLYEVNA LEONCHIK, R.D.H.	8/16/2012
H6308	JOANNE ALIDA TUSTISON, R.D.H.	8/16/2012
H6309	JENNIFER A LONG, R.D.H.	8/16/2012
H6310	DANIELLE LYNN CHAKARUN, R.D.H.	8/16/2012
H6311	CHELSEA L BAKER, R.D.H.	8/16/2012
H6312	FRANCIS VEGERANO, R.D.H.	8/16/2012
H6313	TALISA E TAYLOR, R.D.H.	8/16/2012
H6314	ANDREA M WILKIE, R.D.H.	8/16/2012
H6315	KELDA ALILLIAN FRAZIER, R.D.H.	8/21/2012
H6316	JULIE A GRAGG, R.D.H.	8/21/2012
H6317	BRITTANY L PAYNE, R.D.H.	8/21/2012
H6318	ALISHA A ORR, R.D.H.	8/21/2012
H6319	ALYSSA K GARNER, R.D.H.	8/21/2012
H6320	CHRISTIANNA E REANEY, R.D.H.	8/21/2012
H6321	JENNIFER N FOUSE, R.D.H.	8/21/2012
H6322	MASA S YOUNGBLOOD, R.D.H.	8/21/2012
H6323	DOMENICA M MC LAUGHLIN, R.D.H.	8/21/2012
H6324	KARA KLOPFENSTEIN, R.D.H.	8/21/2012
H6325	KIMBERLY A QUEST, R.D.H.	8/21/2012
H6326	JEANETTE PEREZ-VOGT, R.D.H.	8/21/2012
H6327	MICHELLE C RADULESCU, R.D.H.	8/23/2012
H6328	HA T BUI, R.D.H.	8/23/2012
H6329	AMBER SELKOW, R.D.H.	8/23/2012
H6330	TAMMY GREVE-EGAN, R.D.H.	8/23/2012
H6331	SHEENA LYNN BATEMAN, R.D.H.	8/24/2012
H6332	JOHN E GARNACHE, R.D.H.	8/28/2012
H6333	AIMEE R ELROD, R.D.H.	8/28/2012
H6334	FAREN G CALDWELL, R.D.H.	8/28/2012
H6335	CHELSEY A VANDEWALL, R.D.H.	8/28/2012
H6336	AMANDA E BOLLIGER, R.D.H.	8/28/2012
H6337	HOLLY A ARNOLD, R.D.H.	8/28/2012
H6338	FOZIA A MOHAMED, R.D.H.	8/28/2012
H6339	KIM SUZANN VIAN, R.D.H.	8/28/2012
H6340	LISA A SOLTANI, R.D.H.	9/13/2012
H6341	DANYELL G BROOKBANK, R.D.H.	9/13/2012
H6342	AMANDA J HIGNELL, R.D.H.	9/13/2012

H6343	KYLIE N ANTOLINI, R.D.H.	9/13/2012
H6344	CHANTELLE S MOLLERS, R.D.H.	9/13/2012
H6345	KELSEY M FENSTEMACHER, R.D.H.	9/13/2012
H6346	ANNA M KOROTEYEV, R.D.H.	9/13/2012
H6347	AMANDA L LANGENHUYSEN, R.D.H.	9/13/2012
H6348	ELIZA M BROEHL, R.D.H.	9/13/2012
H6349	MEAGAN A LIPTAK, R.D.H.	9/13/2012
H6350	JONNIE L MC BRIDE, R.D.H.	9/13/2012
H6351	THUY TRAN-CHU, R.D.H.	9/13/2012
H6352	ALBINA P BURUNOVA, R.D.H.	9/13/2012
H6353	NICHOLE DAVIDSON, R.D.H.	9/13/2012
H6354	KAREN A WATERS, R.D.H.	9/13/2012
H6355	AMANDA K BLACK, R.D.H.	9/20/2012
H6356	KIMBERLY M HIDAY, R.D.H.	9/20/2012
H6357	LACEY M ULMER, R.D.H.	9/20/2012
H6358	IZUMI K HANSEN, R.D.H.	9/20/2012
H6359	ROBIN W ROSS, R.D.H.	9/20/2012
H6360	TANIA CAROLINA ROJERO SANCHEZ, R.D.H.	9/20/2012
H6361	DAINA A COULSON, R.D.H.	9/20/2012
H6362	MELISSA SMITH, R.D.H.	9/20/2012
H6363	MORGAN A WELLER, R.D.H.	9/20/2012
H6364	EMILY E COOKE, R.D.H.	9/20/2012
H6365	JESSICA J BARTON, R.D.H.	9/20/2012
H6366	ANNA M SHERIDAN, R.D.H.	9/21/2012

Dentists

D9754	ANNE ADAMS-BELUSKO, D.M.D.	7/20/2012
D9755	JORDAN R TAKAKI, D.M.D.	7/20/2012
D9756	THERESA M COLLINS, D.M.D.	7/20/2012
D9757	KATHRYN ANNE ZOUMBOUKOS, D.M.D.	7/20/2012
D9758	MICHAEL JOHN SPARROW, D.M.D.	7/20/2012
D9759	BRANDON S REHRER, D.D.S.	7/20/2012
D9760	NATASHA M BRAMLEY, D.M.D.	7/24/2012
D9761	DEEPAK DEVARAJAN, D.M.D.	7/24/2012
D9762	EVON T HEASER, D.D.S.	7/31/2012
D9763	STEVEN R SCHMID, D.D.S.	7/31/2012
D9764	CHADWICK D TRAMMELL, D.D.S.	7/31/2012
D9765	RYAN LAYNE REESE, D.M.D.	7/31/2012
D9766	DIANA V BOKOV, D.M.D.	7/31/2012
D9767	JAMES E RUCKMAN, D.M.D.	8/3/2012
D9768	PAUL MICHAEL THORESON BUCK, D.D.S.	8/3/2012
D9769	STEPHEN GEORGE, D.M.D.	8/3/2012
D9770	RICHARD ANDREW ZELLER, D.D.S.	8/3/2012
D9771	JED TAUCHER, D.M.D.	8/3/2012
D9772	THEODORE R RASK, D.M.D.	8/3/2012
D9773	CURTIS A PETERS, D.M.D.	8/10/2012
D9774	SONJA ANN SPROUL, D.D.S.	8/10/2012
D9775	HYUNG MIN C CHA, D.M.D.	8/10/2012
D9776	AARON POGUE, D.M.D.	8/10/2012
D9777	TRISTAN J STONE, D.D.S.	8/16/2012
D9778	GARY MENCL, D.M.D.	8/21/2012

D9779	AARON J RINTA, D.M.D.	8/23/2012
D9780	CAROLYN S CHOI, D.M.D.	8/23/2012
D9781	CHEN CHEN JANE XING, D.M.D.	8/23/2012
D9782	RICHARD M LUBOW, D.M.D.	8/28/2012
D9783	CAROLINE M MAY, D.D.S.	8/28/2012
D9784	RAJESH CHUNDURI, D.M.D.	8/28/2012
D9785	RACHEL M DEININGER, D.D.S.	9/13/2012
D9786	WENLANG ZHANG, D.D.S.	9/13/2012
D9787	ANTON JON CONKLIN, D.M.D.	9/13/2012
D9788	PAUL D HARDMAN, D.M.D.	9/13/2012
D9789	HIRAL SHAH, D.M.D.	9/13/2012
D9790	ROSS U ICYDA, D.M.D.	9/13/2012
D9791	KEVIN J FORD, D.M.D.	9/13/2012
D9792	DEMIAN SCOTT WOYCIEHOWSKY, D.M.D.	9/13/2012
D9793	AMIR F AZARISAMANI, D.M.D.	9/20/2012
D9794	KRISTA A LOWEN, D.D.S.	9/21/2012
DF0025	JAMES A KATANCIK, D.D.S.	9/13/2012

Announcement

No announcements

ADJOURNMENT

The meeting was adjourned at 12:02 p.m. Dr. Parker stated that the next Board meeting would take place December 14, 2012.

Approved by the Board December 14, 2012.

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Patricia Parker, D.M.D.
President

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OREGON BOARD OF DENTISTRY
SPECIAL TELEPHONE CONFERENCE MINUTES
November 2, 2012

MEMBERS PRESENT:	Patricia Parker, D.M.D., President Jonna E. Hongo, D.M.D., Vice-President Alton Harvey, Sr. Julie Ann Smith, D.D.S., M.D. Darren Huddleston, D.M.D. Jill Mason, M.P.H., R.D.H. Norman Magnuson, D.D.S. Mary Davidson, M.P.H., R.D.H.
STAFF PRESENT:	Patrick D. Braatz, Executive Director Paul Kleinstub, D.D.S., M.S., Dental Director/Chief Investigator Harvey Wayson, Investigator Stephen Prisby, Office Manager
ALSO PRESENT:	Lori Lindley, Sr. Assistant Attorney General

Call to Order: The meeting was called to order by the President at 12:00 p.m. at the Board office; 1600 SW 4th Ave., Suite 770, Portland, Oregon. Board Members and Board Counsel were present via telephone.

EXECUTIVE SESSION: The Board entered into Executive Session pursuant to ORS 192.606 (1)(f), (h) and (k); ORS 676.165; ORS 676.175 (1), and ORS 679.320 to review records exempt from public disclosure, to review confidential investigatory materials and investigatory information, and to consult with counsel.

OPEN SESSION: The Board returned to Open Session.

HUSER, SHELLY R., R.D.H. 2009-0105
Mr. Harvey moved and Dr. Smith seconded that the Board issue an Order of Immediate Emergency License Suspension, suspending Licensee's Oregon dental hygiene license, pending further order of the Board and deny Licensee's request for the consideration of a third evaluation. The motion passed with Dr. Hongo, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.
Mr. Harvey moved and Dr. Magnuson seconded that the Board grant Mr. Braatz the authority to sign the Order immediately. The motion passed with Dr. Hongo, Mr. Harvey, Dr. Smith, Dr. Huddleston, Ms. Mason, Dr. Magnuson and Ms. Davidson voting aye.

ADJOURNMENT
The meeting was adjourned at 12:20 p.m.

Approved by the Board December 14, 2012.

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Patricia Parker, D.M.D.
President

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ASSOCIATION REPORTS

Nothing to report under this tab

COMMITTEE REPORTS

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ADEX
AMERICAN BOARD OF DENTAL EXAMINERS, INC.

RECEIVED
DEC 0 3 2012
Oregon Board of Dentistry

Bruce Barrette, D.D.S., President
Stanwood Kanna, D.D.S., Vice-President
William Pappas, D.D.S., Secretary
Robert Jolly. DDS, Treasurer
Guy Shampaine, D.D.S., Past President

To: State Boards and Dental Schools

This advisory is being sent to briefly describe the 2013 American Board of Dental Examiners (ADEX) examination in dentistry including a listing of the four examinations that must be passed (with a score of 75 or greater) to achieve "ADEX status" and also "NERB status".

The ADEX Dental Examination is the examination approved by American Board of Dental Examiners, Inc. and is adopted and administered by NERB, SRTA, Florida (administered by the NERB) and Nevada. It consists of a series of clinical examinations, both simulated on computer and manikins as well as clinical performances on patients. These examinations are utilized to assist licensing jurisdictions in making decisions concerning the licensure of dentists.

The 2013 ADEX Dental Examination consists of four required individual, skill-specific clinical examinations: three simulated patient clinical examinations and one clinical examination performed on patients. The three required simulated patient clinical examinations are the computer-based Diagnostic Skills Examination (DSE), the manikin-based Endodontic Clinical Examination, and the Fixed Prosthodontic Clinical Examination. The one required clinical examination performed on patients is the Restorative Clinical Examination which consists of preparing and restoring an anterior and posterior tooth. A candidate is considered to have passed the ADEX examination, and achieved "ADEX status", and "NERB status", when they have passed the four required examinations (the DSE, Prosthodontic, Endodontic and Restorative examinations).

The one optional clinical examination performed on patients is the Periodontal Clinical Examination. ADEX, NERB, SRTA, and Nevada, have just completed a national Occupational Analysis in Dentistry. The survey instrument utilized in the occupational analysis was designed to elicit procedures that dentists perform or supervise, and rank their criticality. The results of this national occupational analysis demonstrate that entry-level dentists while they do perio scaling, the skill is performed less frequently than the supervision of these skills. Literally none of the performance skills tested on the patient based Periodontal Examination were supported for performance testing on the clinical patient-based examination. Therefore the Periodontal Clinical Examination is considered optional by ADEX, but is available to candidates in consideration of specific requirements for licensure in those states that require a clinical examination in Periodontics. Candidate scores for the optional Periodontal examination will be included whenever scores are reported for the required sections of the exam. Note that a failing grade (less than 75) in the optional Periodontal examination does not affect whether a candidate has passed the ADEX examination nor is the candidate required to retake the Periodontal examination (unless they are seeking licensure in a state that requires having passed a clinical Periodontal examination). Many states have not required this skill set performance examination for several years as SRTA has not included this performance examination since 2005.

P.O. Box 8733 • Portland, Oregon 97207-8733
Telephone (503) 724-1104
ADEXOFFICE@aol.com
www.adex.org

The Diagnostic Skills Examination has undergone a total psychometric review, blueprint to realignment, and is a very robust examination on the cognitive skills in diagnosis and treatment planning in Periodontics, a critical skill set for all dentists.

Candidates are encouraged to check with the state dental board in the state where they wish to practice, to determine exactly what is required for licensure in that state.

We hope that this information helps explain the requirements of the 2013 ADEX examination.

Please contact me if you have any questions or concerns.

Sincerely,

Bruce J. Barrette, D.D.S.
President, ADEX

ADEX

American Board of Dental Examiners, Inc.

a test development agency for the member state dental boards

2011-2012 Annual Report

ADEX

American Board of Dental Examiners, Inc.

a test development agency for the member state dental boards

2011-2012 Annual Report

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Message from the President

Welcome to the Eighth Annual ADEX House of Representatives. The American board of Dental Examiners (ADEX) has just finished its seventh full year of initial licensure examinations in dentistry and dental hygiene. This has been an especially busy year with much accomplished. Three new states (Virginia, Mississippi and New Mexico) have become members. At the same time, we continue to strengthen our examinations with a special emphasis this year on improving our calibration exercises.

ADEX still remains the largest licensure test development entity for dentistry in the United States with 30 state dental boards as members and with approximately 41 states accepting the examinations for licensure. This progress is due to the support and commitment of the member state boards and the volunteers chosen by those state dental boards toward developing the most valid, reliable and defensible examinations possible for the dental profession.

Thank you for your dedication and participation in the 2012 ADEX House of Representatives.

Bruce Barrette, DDS
President, ADEX

ADEX Membership

Membership gives a recognizing state dental board direct involvement in the development and evolution of the examinations through committee appointments; and approval of the final form of the examinations in dentistry and dental hygiene through their appointments to the House of Representatives.

Consumer members of state dental boards are full active voting members of ADEX directly involved in the evolution and participation of the examinations.

Member Jurisdictions

Arkansas
Colorado
Connecticut
District of Columbia
Florida
Hawaii
Illinois
Indiana
Iowa
Kentucky
Maine
Maryland
Massachusetts
Michigan
Mississippi
New Mexico
Nevada
New Hampshire
New Jersey
Ohio
Oregon
Pennsylvania
Rhode Island
South Carolina
Tennessee
Wyoming
Vermont
Virginia
West Virginia
Wisconsin

ADEX

ADEX Districts

ADEX initial districts were drawn to try to equalize the number of dental students, dentists licensed each year, and to some degree practicing dentist numbers.

District 1:	California
District 2:	Alaska, Arizona, ***Colorado, Hawaii***, Idaho, Montana, ***Nevada***, ***New Mexico***, ***Oregon***, Utah, Washington, ***Wyoming***
District 3:	Kansas, Missouri, Nebraska, Oklahoma, Texas
District 4:	***Iowa***, Minnesota, North Dakota, South Dakota, ***Wisconsin***
District 5:	***Illinois, Indiana, Michigan, Ohio***
District 6:	***Arkansas***, Georgia, ***Kentucky, South Carolina***, ***Tennessee***, ***Virginia, West Virginia***
District 7:	***Maryland, Pennsylvania***
District 8:	***Connecticut***, Delaware, ***District of Columbia***, U.S. Virgin Islands
District 9:	***New Hampshire, New Jersey***, New York, ***Rhode Island***
District 10:	***Maine, Massachusetts, Vermont***
District 11:	Alabama, Louisiana, ***Mississippi***, North Carolina, Puerto Rico
District 12:	***Florida***

States highlighted in ***bold italics*** are Member States

ADEX Governance

Governing Principle

ADEX's governing principle is that the governing authority is vested with the active member state boards of dentistry. Representatives are directly appointed by the active state dental board and the directors elected by state board representatives.

Important committee appointments are directly made through the representatives of the active state dental boards.

House of Representatives

Governance is from the Member State Dental Boards in the House of Representatives.

- The House of Representatives consists of dentist or executive director representatives from the member state dental boards. They hold final approval of major examination changes.

- Each state board will designate one representative.

- Representatives are required to have been active voting board members of the member state at some time.

- A Dental Hygiene representative from each ADEX district is required to be or have been an active board member from a member state.

- A Consumer representative from each ADEX district is required to be or have been an active board member from a member state.

- Each state will determine the qualifications of their representative.

- Members from American Dental Association (ADA), American Student Dental Association (ASDA), American Dental Education Association (ADEA), American Dental Hygienists' Association (ADHA), The National Dental Examining Board of Canada (NDEB), Canadian Dental Association (CDA), National Board of Medical Examiners (NBME), and Federation of State Medical Boards (FSMB) are chosen by their respective organizations.

2011 ADEX House of Representatives

Dentist or Executive Director Representatives

Colorado – Mr. Maulid Miskell

Connecticut – David Perkins, DDS

District of Columbia – Robert Ray, DMD

Florida – Wade Winker, DDS

Hawaii – Mark Baird, DDS

Illinois – Dennis Manning, DDS

Indiana – Matthew Miller, DDS

Iowa – No Representative

Kentucky – H.M. “Bo” Smith< DDS

Maine – Rockwell Davis, DDS

Maryland – Maurice Miles, DDS

Massachusetts – Mina Paul, DDS

Michigan – William Wright, DDS

Nevada – William Pappas, DDS

New Hampshire – Neil Hiltunen, DMD

New Jersey – Peter DeSciscio, DDS

Ohio – Phil Beckwith, DDS

Oregon – Patricia Parker, DMD

Pennsylvania – John V. Reitz, DDS

Rhode Island – Henry Levin, DDS

South Carolina – Michelle Bedell, DDS

Vermont – Richard Dickinson, DDS

West Virginia – Craig Meadows, DDS

Wisconsin – Dr. Keith Clemence, DDS

Wyoming – Scott Houfek, DDS

2011 ADEX House of Representatives (cont.)

Dental Hygiene Representatives

Mary Davidson, RDH, MPH, OR	District 2
Nan Dreves, RDH, MBA, WI	District 4
Mary Johnston, RDH, MI	District 5
Dina Vaughn, BSDH, MS, WV	District 6
Cheryl Bruce, RDH, MD	District 7
Sibyl Gant, RDH, DC	District 8
Nancy St. Pierre, RDH, NH	District 9
Karen Dunn, RDH, MA	District 10
Irene Stavros, RDH, FL	District 12

Consumer Representatives

Marian Grey, HI	District 2
Ms. Judith Ficks, WI	District 4
Ms. Clance LaTurner, IN	District 5
Mr. Allan D. Francis, KY	District 6
Allan Horwitz, Esq., PA	District 7
No Representative	District 8
Ms. Lynn Joslyn, NH	District 9
Ms. Diane Denk, ME	District 10
Ms. Vicki Campbell, FL	District 12

2011 ADEX House of Representatives (cont.)

Associate Members

American Dental Association – Samuel Low, DDS, ADA Trustee

American Student Dental Association – Mr. Ken Randall, President

American Dental Education Association – Peter Robinson, DDS

American Dental Hygienists' Association – No Representative

National Dental Examining Board of Canada – No Representative

Canadian Dental Association – No Representative

Federation of State Medical Boards – No Representative

National Board of Medical Examiners –No Representative

ADEX Board of Directors

ADEX Officers

Bruce Barrette, DDS	Wisconsin	President
Stanwood Kanna, DDS	Hawaii	Vice-President
William Pappas, DDS	Nevada	Secretary
H.M. “Bo” Smith, DMD	Arkansas	Treasurer
Guy Shampaine, DDS	Maryland	Immediate Past President

ADEX Board of Directors – Up to 17 Members

12 Districts, Examination Committee Chairs, Dental Hygiene Representatives

Directors elected by state board representatives in House of Representatives

Board of Directors

Stan Kanna, DDS	Hawaii	District 2
Bruce Barrette, DDS	Wisconsin	District 4
M.H VanderVeen, DDS	Michigan	District 5
Michelle Bedell, DMD	South Carolina	District 6
Guy Shampaine, DDS	Maryland	District 7
Robert Ray, DMD	DC	District 8
Peter DeSciscio, DMD	New Jersey	District 9
Richard Dickinson, DDS	Maine	District 10
Jeffrey Hartsog, DDS	Mississippi	District 11
Wade Winker, DDS	Florida	District 12
Ms. Judith Ficks	Wisconsin	Consumer Member
Mr. Zeno St. Cyr, II	Maryland	Consumer Member
Cathy Turbyne, EdD, MS, RDH	Maine	Hygiene Member
James “Tuko” McKernan, RDH,	Nevada	Hygiene Member
Nancy St. Pierre, RDH,	New Hampshire	Chair, Dental Hygiene Examination Committee
Scott Houfek, DDS	Wyoming	Chair, Dental Examination Committee

Terms for Current ADEX Board of Directors*

District	Incumbent	Remaining Tenure
District 2	Stan Kanna, DDS	0 Year
District 4	Bruce Barrette, DDS	0 Year
District 5	M. H. VanderVeen, DDS*	1 Years
District 6	Michelle Bedell, DMD*	2 Years
District 7	Guy Shampaine, DDS	0 Year
District 8	Robert Ray, DMD	1 Years
District 9	Peter DeSciscio, DMD	1 Years
District 10	Richard Dickinson, DDS	2 Years
District 11	Jeffrey Hartsog, DDS*	0 Year
District 12	Wade Winker, DDS*	2 Years
Consumer Member	Ms. Judith Ficks	1 Years
Consumer Member	Mr. Zeno St. Cyr, II	0 Year
Hygiene Member	Cathy Turbyne, EdD, MS, RDH	0 Year
Hygiene Member	James “Tuko” McKernan, RDH*	1 Years

* members of the Board of Directors are eligible to serve a second three-year term if elected by their district.

ADEX Committees

Dental Examination Committee

- One (1) dentist from each Member Board.
- One (1) Member Board consumer representative
- 1 Consumer
- The Chair of the Dental Examination Committee
- All appointments are nominated by the representatives of the member state dental boards.

Dental Examination Committee Members

Scott Houfek, DDS, WY – Chair

District 2: (CO, HI, NV, OR, WY)
Peter Carlesimo, DDS, CO
Stan Kanna, DDS, HI
William Pappas, DDS, NV
Jonna Hongo, DMD, OR
TBD, WY
Rick Thiriot, DDS, NV Educator

District 4: (IA, WI)
Gary Roth, DDS, IA
Keith Clemence, DDS, WI
Leo Huck, DDS, WI Educator

District 5: (IL, IN, MI, OH)
Dennis Manning, DDS, IL
Matthew Miller, DDS, IN
Chuck Marinelli, DDS, MI
Eleanore Awadalla, DDS, OH
Peter Yaman, DDS, MI, Educator

Dental Examination Committee Members (cont.)

District 6: (AK, KY, SC, TN, WV)
- George Martin, DDS, AR
- Robert Zena, DDS, KY
- Michelle Bedell, DDS, SC
- John M. Douglas, Jr. DDS, TN
- James Watkins, DDS, VA
- John Dixon, DDS, WV
- Rick Archer, DDS, VA Educator Rep

District 7: (MD, PA)
- Guy Shampaine, DDS, MD
- Susan Calderbank, DMD, PA
- Uri Hangorski, PA, Educator

District 8: (CT, DC)
- David Perkins, DMD, CT
- Rahele Rezai, DMD, DC
- John Bailey, DDS, DC, Educator

District 9: (NH, NJ, RI)
- Barbara Rich, DMD, NJ
- Arthur McKibbin, Jr., DMD, NH
- Henry Levin, DMD, RI
- Marc Rosenblum, DMD, NJ, Educator

District 10: (ME, MA, VT)
- Robert DeFrancesco, DMD, MA
- LeeAnn Podruch, DDS, VT
- Rockwell Davis, DDS, ME
- Stephen DuLong, DMD, MA, Educator

District 11: (AL, LA, MS, NC, PR)
- A. Roddy Scarbrough, DMD, MS
- Larry C. Breeding, DMD, MS, Educator

District 12: (FL)
- William Kuchenour, DDS, FL
- Boyd Robinson, DDS, FL, Educator

Dental Examination Committee Members (cont.)

Consumer:
Alan Horwitz, Esq., PA

Testing Specialist:
Steven Klein, Ph.D, CA

Ex-Officio:
Bruce Barrette, DDS, WI ADEX President

NERB Administrative Liaison:
Ronald Chenette, DMD, MD

Nevada Administrative Liaison:
Kathleen Kelly, NV

SRTA Administrative Liaison:
Kathleen White, VA

ADEX Committees (cont.)

Dental Hygiene Examination Committee

- 1 Dental Hygienist from each district
- 1 Dental Hygiene Educator
- 1 Dentist
- 1 Consumer
- All appointments are nominated by the active member state dental boards.

Dental Hygiene Examination Committee Members

Nancy St. Pierre, RDH, NH – Chair

District 2: Jill Mason, RDH, MPH, OR

District 4: Nanette Kosydar Dreves, RDH, MBA, WI

District 5: Lynda Sabat, RDH, OH

District 6: Diana Vaughan, RDH WV

District 7: Marellen Brickley-Raab, RDH, PA

District 8: Judith Neely, RDH, BS, DC

District 9: Shirley Birenz, RDH, BS, NJ

District 10: Karen Dunn, RDH, MA

District 11: Janet Brice McMurphy, RDH, MS

District 12: Irene Stavros, RDH, FL

Dentist: Maxine Feinberg, DDS, NJ

Educator: Donna Homenko, RDH, PhD, OH

Consumer: Zeno St. Cyr II, MPH, MD

NERB Administrative Liaison: Ellis Hall, DDS, MD

NERB Administrative Liaison: Michael Zeder, MD

Testing Specialist: Steven Klein, Ph.D, CA

ADEX President - Ex-Officio, Bruce Barrette, DDS, WI

ADEX Committees (cont.)

Budget Committee

H. M. “Bo” Smith, DMD, AR - Chair
Scott Houfek, DDS, WY
Neil Hiltunen, DDS, NH
Tony Guillen, DDS, NV
Guy Shampaine, DDS, MD
Charles Ross, DDS, FL
Kathleen White, VA
Bruce Barrette, DDS, WI - ADEX President Ex-Officio

Bylaws Committee

Robert Ray, DDS, WI - Chair
Garo Chalian, DDS, CO
James “Tuko” McKernan, NV
Alan Horowitz, Esq., PA
Bruce Barrette, DDS, WI - ADEX President Ex-Officio

Calibration Committee

William Pappas, DDS, NV - Chair
Scott Houfek, DDS, WY
Tony Guillen, DDS, NV
Rick Thiriot, DDS, NV
Neil Hiltunen, DDS, NH
Ogden Munroe, DDS, IL
Ken Van Meter, DDS, VT
Rick Kewlowitz, DDS, FL
Wendell Garrett, DDS, AR
Ronald Chenette, DMD, MD
Richard Marshall, DDS, WV
Peter Yaman, DDS, MD
Bruce Barrette, DDS, WI - ADEX President Ex-Officio

Communications Committee

Mary Johnston, RDH, MI - Chair
Stanwood Kanna, DDS, HI
Kathy Heier, RDH, IL
Mary Davidson, RDH, OR
Clance LaTurner, IN
Bruce Barrette, DDS, WI - ADEX President Ex-Officio

Quality Assurance Committee

Hal Haering, DDS, AZ - Chair
Stanwood Kanna, DDS, HI
Patricia Parker, DMD OR
Robert Sherman, DDS, HI
J. George Kinnard, DDS, NV
Barbara Rich, DMD, NJ
Nan Kosydar Dreves, RDH, MBA, WI
James Haddix, DMD, FL
Guy Shampaine, DDS, MD
Richard Marshall, DDS, VA
Kathleen White, VA
Ronald Chenette, DMD, MD
Scot Houfek, DDS, WY
Nancy St. Pierre, RDH, NH
Bruce Barrette, DDS, WI - ADEX President Ex-Officio

ADEX Dental Examination

Content

- Five stand alone examinations
    - Critical skill sets identified by criticality in the Occupational Analysis
- Computerized Examination in Applied Diagnosis and Treatment Planning
- Endodontic Clinical Examination
    - Manikin-based
- Fixed Prosthodontic Clinical Examination
    - Manikin-based
- Restorative Clinical Examination
    - Patient-based
- Periodontal Clinical Examination
    - Patient-based

Scoring

- Criterion based scoring system
- Three (3) independent raters without collaboration

Rating Levels

- Satisfactory
- Minimally Acceptable
- Marginally Substandard
- Critically Deficient

ADEX Dental Exam Scoring

Criterion-Based Analytical Scoring Rubric:

- More detailed feedback.
- More consistent scoring.
- Allows for the separate evaluation of factors.
- Evaluation of all gradable criteria.
- Scoring methodologies were developed with consultation from the Buros Institute, University of Nebraska and the Rand Institute with input from studies completed by testing specialists from the University of Chicago.
- Three (3) independent raters evaluate all measurable criteria.
- Median score is utilized when there are no matching scores; all zeros must be independently corroborated to be utilized as a critical deficiency.
- Performance criteria-based scoring will be provided to both the candidate and the dental school so that appropriate remediation can be completed prior to a retake when required.
- Clinical sections utilize compensatory grading with critical errors within a skill set.
- No grading across skills.
- Critical errors are those performance deficiencies that would cause treatment to fail. A critical error forces a failure on that skill set examination. Not all criteria have critical errors.

Evaluation Criteria

Objective measurable criteria developed by a panel of experts consisting of examiners, practitioners, and educators.

Amalgam Prep External Outline Criteria (Example)

SATISFACTORY

1. Contact is visibly open proximally and gingivally up to 0.5 mm.
2. The proximal gingival point angles may be rounded or sharp.
3. The isthmus must be 1-2 mm wide, but not more than ¼ the intercuspal width of the tooth.
4. The external cavosurface margin meets the enamel at 90°. There are no gingival bevels. The gingival floor is flat, smooth and perpendicular to the long axis of the tooth.
5. The outline form includes all carious and non-coalesced fissures, and is smooth, rounded and flowing.
6. The cavosurface margin terminates in sound natural tooth surface. There is no previous restorative material, including sealants, at the cavosurface margin. There is no degree of decalcification on the gingival margin.

MINIMALLY ACCEPTABLE

1. Contact is visibly open proximally, and proximal clearance at the height of the contour extends beyond 0.5 mm but not more than 1.5 mm on either one or both proximal walls.
2. The gingival clearance is greater than 0.5 mm but not greater than 2 mm.
3. The isthmus is more than ¼ and not more than 1/3 the intercuspal width.
4. The proximal cavosurface margin deviates from 90°, but is unlikely to jeopardize the longevity of the tooth or restoration; this would include small areas of unsupported enamel.

MARGINALLY SUBSTANDARD

1. The gingival floor and/or proximal contact is not visually open; or proximal clearance at the height of contour extends beyond 1.5 mm but not more than 2.5 mm on either one or both proximal walls.
2. The gingival clearance is greater than 2 mm but not more than 3 mm.
3. The outline form is inappropriately overextended so that it compromises the remaining marginal ridge and/or cusp(s).
4. The isthmus is less than 1 mm or greater than 1/3 the intercuspal width.
5. The proximal cavosurface margin deviates from 90° and is likely to jeopardize the longevity of the tooth or restoration. This would include unsupported enamel and/or excessive bevel(s).
6. The cavosurface margin does not terminate in sound natural tooth structure; or, there is explorer penetrable decalcification remaining on the cavosurface margin, or the cavosurface margin terminates in previous restorative material. *(See glossary under Previous Restorative Material).*
7. There is explorer-penetrable decalcification remaining on the gingival floor.
8. Non-coalesced fissure(s) remain which extend to the DEJ and are contiguous with the outline form.

CRITICAL DEFICIENCY

1. The proximal clearance at the height of contour extends beyond 3 mm on either one or both proximal walls.
2. The gingival clearance is greater than 3 mm.
3. The isthmus is greater than ½ the intercuspal width.
4. The outline form is overextended so that it compromises, undermines and leaves unsupported the remaining marginal ridge to the extent that the pulpal-occlusal wall is unsupported by dentin or the width of the marginal ridge is 1 mm or less.

Endodontic Clinical Examination on a Simulated Patient (Manikin)

Part II: Endodontics – 18 Scorable Items

- Anterior Endodontic Procedures — 12 Criteria
  - Access Opening
  - Canal Instrumentation
  - Root Canal Obturation
- Posterior Access Opening — 6 Criteria

Fixed Prosthodontic Examination on a Simulated Patient (Manikin)

Part III: Fixed Prosthodontics – 43 Scorable Items

- Cast Gold Crown — 15 Criteria
- Porcelain-Fused-to-Metal Crown — 14 Criteria
- Ceramic Crown Preparation — 14 Criteria
- Preparations 1 & 2 evaluated as a mandibular posterior 3-unit bridge

Part V: Restorative – 47 Scorable Items

- Class II Amalgam Preparation — 16 Criteria
- Amalgam Finished Restoration — 9 Criteria
- Class III Composite Preparation — 12 Criteria
- Composite Finished Restoration — 10 Criteria

Periodontal Clinical Examination

<u>Treatment Selection (Procedural)</u>

- Patient Selection severity of periodontal disease.

<u>Treatment</u>

1. Subgingival Calculus Detection
2. Subgingival Calculus Removal
3. Plaque/Stain Removal
4. Pocket Depth Measurement
5. Treatment Management

ADEX Dental Post-Exam Analysis

- Technical Report Developed
- Demographic Data/Analysis
  - Conducted by respective administering agencies
  - Synopsis of data provided for Restorative and Periodontal Procedures with several years of history:

Demographic Data on the Candidate Pool

Failure Rate Summaries

Analysis of Candidate Performance by Test Section

Analysis of Failure Rates by Group Assignment

Analysis of Mean Scores by Procedure/Examination Part

Examiners' Score Agreement Summary

Frequency of Rating Assignments

Correlation of Treatment Selection with Restorative Results

Frequency of Penalty Assignments

Annual Schools Report

- Schools are provided with data regarding their performance annually
- Schools are provided individual candidate performance after each examination series.
- School identities are coded so that each school may compare their performance confidentially
- Performance data for each area of examination content is analyzed and presented
- By procedure
- By individual criterion

Examiner Profiles

- Data is collected for each examiner and compiled into profiles providing information to the examiners regarding their evaluations.

Summary of Total Number of Evaluations per Dental Examiner

Summary of Examiner Agreements for each Examination/Procedure

Percentage Rating Level Assigned per Procedure

Summary of Examiner Agreements & Disagreements across all Procedures

Peer Evaluations

- This information is utilized to monitor examiner performance

TECHNICAL ANALYSIS OF ADEX RESULTS: 2011-2012

Prepared by Stephen Klein, Ph.D. and Roger Bolus, Ph.D.

I. Examination Structure and Rules

Passing the ADEX test battery in 2012 was accepted by 47 states as evidence that a candidate seeking licensure to practice dentistry had acquired the knowledge, skills, and abilities that are necessary for providing safe and appropriate care. Candidates also must satisfy specific state educational and other requirements to be licensed.

Examination Components, Administration, and Format. The ADEX test battery consists of five separate tests: Diagnostic Skills Examination (DSE), Endodontics, Fixed Prosthodontics, Periodontics, and Restorative.

The DSE is a computer based enhanced multiple choice test. Many of its items require candidates to make judgments about clinical conditions based on radiographs, photographs, laboratory data, and working models that are displayed on the candidate's computer screen. This one-day test is administered at professional test centers across the country.

The other four measures are performance tests that are administered using standardized dental instruments and performed at work stations at accredited dental schools. These work stations correspond to ones typically used in practice. The Endodontics and Fixed Prosthodontics tests involve candidates working on manikins that are specially constructed and standardized for the ADEX. A candidate typically takes one of the four performance tests in the morning and another in the afternoon. The Restorative and Periodontics tests are given on one day and the other two performance tests on another day.

Case Acceptance. The Periodontics and Restorative care tests involve live patients who are recruited by the candidates. On the restorative test, two examiners independently review each patient to determine the patient's suitability for treatment, that is, that the patient has the necessary oral conditions to be treated, the appropriate diagnosis and treatment plan is in place, and the medical history does not contain any counter indications for treatment. If the first two examiners do not agree about the patient's suitability, a third examiner is called to break the tie. The ADEX Technical Manual (which is available on the web) describes each test's operational procedures, specifications, and scoring and decision rules.[1]

Dental Examiners. The quality of a candidate's work on each of the four performance tests is evaluated by three specially trained dentists. They record their judgments on an electronic tablet that is programmed for this purpose. The examiners work independently (e.g., they do not discuss the quality of a candidate's performance with the other examiners or the patient). To preserve anonymity and independence, examiners do not see or interact with the candidates and they do not watch the candidate perform the work.

[1] Case acceptance on the Periodontics exam is discussed later in this report.

Pass/Fail Rules. Candidates must pass all five tests to receive ADEX certification and they must repeat all the parts and sections of any test they fail. A high score on one performance test or test section cannot offset a low score or failing status on another test. Candidates are allowed to retake the exams they failed during the August through May testing window, but they cannot carry a passing status on a test across windows. They must pass all five tests within a window to pass overall.

If in the judgment of at least two examiners the candidate made a critical error or deficiency on a live patient, the candidate is excused from continuing the test and receives a failing grade on it. If that happens, the condition of the candidate's patient is temporized and where appropriate, patients are counseled to have any problems with their oral condition addressed by a licensed professional.

Analysis Sample and Testing Window. Except as noted otherwise, results are based on the roughly 1,548 candidates who took all five tests with the Curriculum Integrated Format (CIF) for the first time between August 1, 2011 and May 31, 2012.[2] Results are based on examinations administered by NERB and the Nevada State Board of Dental Examiners.

II. Pass/Fail Decisions

This report focuses mainly on pass/fail decisions (rather than scores) because (1) all the tests were designed to make that type of decision and (2) candidates had to pass each exam to pass overall.

Table 1-A shows the percentage of candidates passing each test on their first attempt and by their last attempt (i.e., if they failed initially and took the exam again). For example, 96.8% passed the DSE on their first try and 98.8% passed after taking this test at least one more time. Most but not all of those failing an exam elected to repeat it.

Table 1-A
Number of Candidates Taking Each Test and Percent Passing

Test	% Pass on 1st Attempt	% Pass by last Attempt	% Did Not Repeat after Initial Fail
DSE	96.8	98.8	1.0
Endodontics	96.8	99.9	0.1
Fixed Prosthodontics	94.1	99.9	0.0
Periodontics	96.9	99.6	0.2
Restorative Dentistry	86.8	97.7	0.5
Mean	94.3	99.2	0.4

On the Restorative exam, all candidates had to perform an anterior composite restoration and a posterior restoration. However, for the posterior restoration, they could choose to do an amalgam, a box composite, or a conventional restoration. Candidates were classified as having chosen an option if they had a non-zero score or a critical error or deficiency

[2] N's vary slightly across analyses as a result of merging of diverse data sets.

associated with that option. The 27 candidates (1.8% of the total) who did not perform any type of posterior restoration were assumed to have taken and failed the anterior composite and therefore were not allowed to continue (see Table 1-B).

Table 1-B
Number of Candidates Taking and Percent Passing Each Restorative Option

Restorative Test Options	Number of Candidates	% Pass
Anterior Test Only	27	0.0
Anterior w. Amalgam	922	88.1
Anterior w. Box Composite	251	90.8
Anterior w. Conventional Composite	340	88.8

The small differences in passing rates among the three restorative options may stem from inherent differences in the difficulty of these procedures, differences in grading standards among the options, differences in the skills of the applicants who select one option over another, chance, or some combination of these and other factors.

The restorative exam had the most influence on a candidate's overall pass/fail status because for most applicants, it was the most difficult one to pass. This was true regardless of which option they selected. Slightly over 75% of the candidates passed the entire exam (all five tests) on their first attempt and 96% passed after repeating one or more tests. Thus, 4% did not pass despite having the option of retaking the exam.

Table 2 shows the median (50th percentile) score on each test. Medians (rather than means) are reported because the zero's assigned to critical errors and deficiencies skew the score distributions.

Table 2
Median Scores by Exam for First Timers

Test	Median
DSE	86.0
Endodontics	98.0
Fixed Prosthodontics	95.0
Periodontics	100.0
Restorative	96.0

Examiners may classify a portion of a procedure within a section (such as "proper placement of the access opening") as critically deficient (DEF) or they may indicate a critical error for the section as a whole, such as saying the candidate treated the wrong tooth or tooth surface. If two or more examiners agree the candidate made a particular type of critical error or DEF, then such corroboration results in the candidate failing the exam.

Table 3 shows that with the exception of the Periodontics exam, only a very small percentage of first timers failed a test without having a critical deficiency or committing at least one corroborated critical error (i.e., few failed because of a low point total). And, no one with even an uncorroborated DEF or critical error passed the Endodontics or fixed Prosthodonitics exam.

Table 3
Role of Critical Errors and Deficiencies in Pass/Fail Decisions

Test	Fail with Critical Error		Fail without Critical Error	
	N	%	N	%
Endodontics	46	3.0	3	0.2
Fixed Prosthodontics	90	5.8	1	0.1
Periodontics	13	0.8	35	2.3
Restorative	179	11.6	19	1.2

Table 4 shows that because of the very high passing rates on all the tests, there was little or no correspondence in their pass/fail decisions other than what would occur by chance. For example, the chance agreement rate was usually less than one percentage point lower than the actual agreement rate.[3] This finding supports the policy of requiring that applicants pass all five tests in the ADEX battery in order to pass overall.

Table 4
Actual and Chance Agreement in Pass/Fail Decisions Between Examinations

Test Combination	**Actual Agreement Rate**	**Chance Agreement Rate**	**Difference in Agreement Rates**
DSE & Endodontics	94.0	93.8	0.2
DSE & Prosthodontics	92.1	91.3	0.8
DSE & Periodontics	94.2	93.9	0.3
DSE & Restorative	85.7	84.4	1.3
Endodontics & Prosthodontics	91.9	91.3	0.6
Endodontics & Periodontics	94.1	93.9	0.2
Endodontics & Restorative	85.0	84.4	0.6
Prosthodontics & Periodontics	91.4	91.4	0.0
Prosthodontics & Restorative	82.3	82.5	-0.2
Periodontics & Restorative	85.2	84.5	0.7
Average	89.6	89.1	0.5

[3] The chance agreement rate between two tests is the product of their passing rates plus the product of their failure rates. For example, if the passing rates on the Endodontics and Prosthodontics exams were 95.5 and 94.5%; then their chance agreement rate would be [(.955 x .945) + (.045 x .055)] = 90.5%.

Table 5 shows the reliability (coefficient alpha) of the scores on each test. These values indicate that the very low correlations between tests were not due to score reliability problems. In addition, as a result of the combination of very high pass rates and adequate score reliabilities, an applicant's pass/fail status is unlikely to change simply by chance (i.e., as distinct from being better prepared).[4] This is referred to as "decision consistency" in the psychometric literature. Analyses were based on the candidates who took all four performance tests and the DSE.

Table 5
Number of Items per Test and Internal Consistency Reliability

Test	Number Of Items	Number of Candidates	Reliability
Endodontics	24	1,522	0.505
Periodontics	37	1,536	0.627
Prosthodontics	43	1,527	0.826
Restorative w. amalgam	54	833	0.655
Restorative w. box	54	234	0.653
Restorative w. conventional	56	308	0.690

III. Inter-Examiner Agreement

Endodontic, Prosthodontic, and Restorative exams. As noted in Table 3, failing one of these tests was driven mainly by whether or not the candidate committed a "critical" error or deficiency. Almost no one failed without committing a corroborated critical error or deficiency; and no one passed who did. A candidate also can fail a test by not earning enough points (the so-called "paper grade") but that almost never occurred except on the Periodonticsl test where it was usually the sole determiner of a candidate's pass/fail status.

The foregoing considerations led us to look at inter-examiner agreement in two ways on the Endodontic, Prosthodontic, and Restorative exams. The first method involved constructing four ratios that focused on the extent to which the examiners agreed the candidate did or did not commit any of the test's possible critical errors or DEFs. For example, there were 21 different types of DEF or critical errors that could be called on the Endodontics test. All four ratios had the same denominator, namely: the number of candidates times the number of possible DEF or critical errors that could be called. The numerator for the first ratio was the total number of patients where all three examiners said there were no DEF or a critical error calls times the number of opportunities for such a call. The numerator for the second ratio was the number of patients where only two of the examiners said there were no DEF or critical error calls times the number of opportunities for making such a call, and so on.

[4] Klein, S., Buckendahl, C., Mehrens, W., & Sackett, P. (2009). Evaluating clinical licensing exams for dentists and dental hygienists. American Board of Dental Examiners. Chicago, IL.

Table 6 shows the examiners achieved consensus 98 to 99 percent of the time. This extremely high rate of decision consistency was due in part to the examiners rarely encountering work that they felt deserved being classified as a critical error or DEF (which is not surprising since almost all the candidates completed dental school). The rates also were inflated due to counting all the DEF and critical error calls that theoretically could be called but were hardly ever made.

Table 6
Percent Agreeing Critical Errors Were or Were Not Present

Test	No Critical Error		With Critical Error	
	% 3/3	% 2/3	% 3/3	% 2/3
Endodontics	99.5	0.4	0.1	0.1
Fixed Prosthodontics	98.6	1.2	0.0	0.2
Restorative w. amalgam	97.8	1.7	0.1	0.3
Restorative w. box	98.7	1.1	0.0	0.2
Restorative w. conventional	97.8	1.9	0.0	0.3

Note: The percentages in a row may not sum to 100.0% due to rounding.

The other way we measured examiner agreement involved calculating how often the three examiners made the same overall decision about a candidate's pass/fail status based on that candidate's "paper grade" which is a function of the number of points the candidate receives and where a score of 75% or higher of the possible maximum score is needed for passing (see Tables 7-A and 7-B). For example, the last row of Table 7-B shows that all three examiners agreed that of the candidates they saw who did a posterior conventional box prep restoration, 58.3% should pass and 8.2% should fail, for an overall perfect agreement rate of 66.5%. In contrast, the perfect agreement rate that was expected to occur by chance was only 48.4%.

Table 7-A
Inter-Examiner Agreement Rates on Endodontics and Prosthodontics

Test	Agree Pass		Agree Fail		Total % Agree	Chance % Agree
	% 3/3	% 2/3	% 3/3	% 2/3		
Endodondtics	91.3	5.6	2.0	1.0	93.4	87.6
Prosthodondtics	72.9	19.1	2.6	5.3	75.5	77.2

Table 7-B
Inter-Examiner Agreement Rates on Restorative Test Options

Restorative Test with Posterior:	Agree Pass		Agree Fail		Total % Agree	Chance % Agree
	% 3/3	% 2/3	% 3/3	% 2/3		
Amalgam	58.2	26.3	9.2	6.3	67.4	47.3
Box	65.9	23.3	6.4	4.4	72.3	56.8
Conventional	58.3	27.2	8.2	6.3	66.5	48.4

It is not clear why the actual degree of agreement between two Prosthodontic examiners (75.5%) was slightly (but not statistically significantly) lower than the chance rate (77.2%). This result came as a surprise since manikins rather than live patients are used for this test. Thus, the lower than expected agreement rate cannot be attributable to variation in patient characteristics. This finding suggests a more in-depth investigation is warranted for this test.

Periodontics. Case acceptance decisions on this test were done sequentially. In stage 1, the floor examiner classified a patient as "acceptable" (i.e., satisfied the case qualification criteria) or not. If "acceptable" the candidate could begin the calculus detection and removal portions of the exam. If the floor examiner determined the patient was not acceptable, then a second examiner evaluated the patient and classified that patient as acceptable or not. If the second examiner said the patient was acceptable, the candidate was cleared for the next portion of the exam. If the second examiner said the patient was not acceptable, the candidate could offer another patient or repeat the exam on another occasion.

There were 17 candidates who were flagged for possible penalty point deductions related to Periodontics case acceptance. The floor examiner flagged two candidates for 30-point deductions, but neither deduction was corroborated by another examiner. The first examiner gave two candidates a 20-point penalty, but only one of those cases was corroborated by a second examiner. The first examiner flagged 13 cases for 5-point penalties, but only 9 of them were corroborated by a second examiner. Thus, all told, only 10 of the 17 candidates that were flagged (59%) actually received penalty point deductions.

On the Periodontics exam itself, two examiners arrived at the same overall pass/fail decision (based on the "paper grade") for about 89% of the candidates. However, because this exam's overall pass rate was so high, the 89% figure is only 2 percentage points greater than what would be expected to occur by chance (such as by simply passing 9 out of every 10 of the candidates they evaluated).

IV. Psychometric Properties of the DSE

The DSE has the following three sections: DOR (Diagnosis, Oral Medicine, and Radioloogy), CTP (Comprehensive Treatment Planning), and PPMC (Periodontics, Prosthosdontics, and Medical Considerations). Responses to the DSE are scored by computer. Examiner judgment is not required.

Table 8 provides summary data on each part of the DSE and the total score. The internal consistency (score reliability) estimates for the DSE were probably dampened by the restricted score range as indicated by the high mean and median scores. Ideally, reliability coefficients should be about 0.90 for this type of test.

Table 8
DSE Statistical Characteristics

Subtest	Number of Items	Mean percent correct	Standard Deviation	Internal Consistency
CTP	80	85.3	5.3	.511
DOR	100	85.5	6.4	.735
PPMC	100	85.7	5.4	.624
Total	280	85.5	4.8	.828

The moderate observed correlations among the three sections (see Table 9) support the policy of having a pass/fail rule for the DSE that allows for some but not total compensatory scoring; i.e., it is appropriate to assign penalty points if the score on one or two of its sections is especially low. The last column of Table 9 shows what the correlations among the sections are likely to be if they were all perfectly reliable (this is called a "correction for attenuation").

Table 9
Observed and Corrected Correlations Between DSE Subtests

Subtests	Observed Correlation	Corrected Correlation
CTP with DOR	.589	.961
CTP with PPMC	.524	.928
DOR with PPMC	.494	.729

We continue to recommend that ADEX monitor whether p-values (percent correct) on repeated items are climbing (which could occur if there was a breach in test security) and explore whether pass/fail decisions can be based on equated rather than raw scores.

STATISTICAL ANALYSIS OF THE 2012 DENTAL HYGIENE EXAM

Stephen Klein, Ph.D. and Roger Bolus, Ph.D.
October 24, 2012

This report provides summary results on ADEX's Clinical Hygiene Examination and on its Computer Simulated Clinical Examination (CSCE) for dental hygienists. Results are for the 2,124 candidates who took both tests for the first time between April and August 2012.

A total score of 75 or higher is needed for passing each test. The percent passing the clinical exam, the CSCE, and both tests on the first try were: 93.5, 93.1 and 87.2 percent, respectively.

Clinical Exam Scoring Rules

Table 1 shows the number of points candidates could receive on each part of the clinical exam. A candidate's score on a part is the median of the scores assigned by three independent examiners. The first two scores are for the "Pre-treatment" portion of the exam and the last three are for the "Post-treatment" portion. The total score is the sum of the five part scores minus any penalty points. Appendix A describes the point deductions that could be assigned.

Table 1
Possible Points In Each Section

Section	Number of judgments	Points per judgment	Total Points
Pocket Depth Measurement	12	1.5	18
Calculus Detection	12	3.0	36
Calculus Removal	12	3.0	36
Plaque/Stain Removal	6	1.0	6
Hard/Soft Tissue	2	2.0	4
Total			100

Table 2 shows the mean score and standard deviation on each part. A comparison of these means with the corresponding maximum possible scores indicates that most candidates had perfect or near perfect scores on each part. Nevertheless, the reliability (coefficient alpha) of the total score was 0.80, which is high given that (a) candidates may have had different examiners for the pre- and post-treatment sections and (b) there was a significant restriction in the range of scores assigned.

Table 2
Summary Test Statistics by Performance Test Section

Exam Section	Maximum Score	Mean Score	Standard Deviation	Score Reliability
Pocket Depth Measurement	18	17.54	1.15	.54
Calculus Detection	36	34.77	3.46	.77
Calculus Removal	36	32.94	4.75	.68
Plaque/Stain Removal	6	5.98	0.17	.26
Hard/Soft Tissue	4	3.89	0.31	.01
Total Score	100	93.90	10.50	.80

Penalty points were not included in these calculations. A candidate's final score on an item corresponded to the score that at least two of the three examiners assigned.

Effect of Penalties

Table 3 shows the number and percentage of candidates that lost points for the reasons noted in Appendix A, such as making a pocket depth qualification error. It also shows the number and percent that failed the exam because of these errors; i.e., these candidates would have passed were it not for the penalties they received. The policy of imposing only the largest applicable penalty (rather than the sum of all the separate ones assigned to the candidate) had no effect on the passing rate. No candidate received a deficient (def) score for hard or soft tissue and there were no pocket depth *measurement* penalties. The mean total clinical score before and after penalty points were awarded were 95.1 and 94.0, respectively.

Table 3
Percentage of Candidates Receiving Penalty Points

	All candidates		Candidates failing because of penalty	
Received penalty for:	N	Percent	N	Percent
Case Acceptance	54	2.5	1	0.0
Pocket Depth Qualification	16	0.8	1	0.0
Calculus Detection	59	2.8	8	0.4
Calculus Removal	76	3.6	72	3.4
Any section	205	9.7	82	3.9

Inter-Examiner Agreement

Each candidate's work on the Clinical Examination was evaluated by three independent examiners (i.e., the examiners made their judgments without consultation with each other or knowing the scores assigned by other examiners). Table 4 shows that despite the extreme restriction in range noted in Table 2, there was still an adequate overall correlation between examiners in the scores they assigned.[1]

Table 4
Mean Correlation Between Two Examiners on Each
Clinical Examination Section and Overall

Exam Section	Correlation
Pocket Depth Measurement	0.415
Calculus Detection	0.391
Calculus Removal	0.311
Plaque/Stain Removal	0.082
Hard/Soft Tissue	0.100
Total	0.330

Another way to look at examiner agreement is to see how often different examiners would make the same pass/fail decision about an applicant. This analysis (which did not consider penalty points) found that 86.3% of the applicants received a passing grade from all three examiners and 0.6% percent received a failing grade from all three. The total perfect agreement rate was therefore 86.9% (see Table 5). however, an 86.9% agreement rate is only 3.3 percentage points higher than the rate that would occur by chance alone.[5]

Table 5
Percent Agreement in Overall Pass/Fail Decisions Among
the First, Second, and Third Examiners

3/3 Agree Pass	2/3 Agree Pass	3/3 Agree Fail	2/3 Agree Fail	% All agree	% All Agree by Chance
86.3	10.6	0.6	2.5	86.9	83.6

[5] The chance rate is the product of the average of the three examiners' individual passing rates. Specifically, the first, second, and third examiners had passing rates of 93.8%, 94.4%, and 94.6%, respectively. The product of these three rates was 83.6%. Analyses were not conducted of the degree to which different examiners and Hygiene Coordinators would make the same decisions regarding case acceptance, the assignment of penalty points, or tooth selection for pocket depth measurements.

Comparison of Clinical and CSCE Statistics

Table 6 shows that 87.2% of the candidates passed both tests and 0.6% failed both for an overall agreement rate of 87.8%. However, given the marginal totals, this is very close to the agreement rate that would occur by chance.[6]

Table 6
Correspondence in the Percentage of Pass/Fail Decisions
Between the Clinical and CSCE Exams

	Fail Clinical	Pass Clinical	Total
Fail CSCE	0.6	6.3	6.9
Pass CSCE	5.9	87.2	93.1
Total	6.5	93.5	100.0

There was a very low correlation between CSCE and Clinical Examination scores (r = 0.104). If this correlation is corrected for the less than perfect reliability of the measures, it would still be only 0.133. In short, the degree of agreement in pass/fail decisions and scores between these two tests was not much higher than what would occur by chance alone.

Table 7 shows that the very low correlation between the Clinical and CSCE was **not** the result of their scores being unreliable. They both had adequate reliabilities (coefficient alphas) for making pass/fail decisions, especially given their high passing rates. Taken together, these findings support ADEX's use of a "conjunctive" rule (i.e., a rule that requires candidates to pass both tests in order to pass overall) rather than a "compensatory" rule (that would allow candidates to offset a low score on one test with a high score on the other).

Table 7
Summary Test Statistics for the Clinical and CSCE Exams

Test	Mean	Median	Standard Deviation	Reliability
Clinical	93.9	97.0	10.5	.80
CSCE	85.4	86.0	6.8	.77

Clinical scores are after penalty points were imposed.

[6] Data on repeaters were not analyzed for this report.

Appendix A
Clinical Exam Penalty Point And Disqualification Rules

Case Acceptance

There are five case acceptance criteria, the first four of which are initially evaluated by a single examiner and have 2 to 4 scoring levels. The fifth criterion, Pocket Depth Qualification, is evaluated by three examiners. The five criteria are:

- Required Forms (SAT, ACC, SUB, or DEF)
- Blood Pressure (SAT, ACC, or DEF)
- Radiographs (SAT, ACC, SUB, or DEF)
- Teeth Deposit Requirements (SAT or ACC)
- Pocket Depth Qualification

No penalty points are deducted if the first examiner assigns a SAT to all of the first four of these criteria. However, if the examiner assigns a non-SAT score to one or more of them, then a second examiner is called in to evaluate all four criteria. If the two examiners agree on a non-SAT call, then that call stands. The point deductions for a corroborated ACC, SUB, and DEF call are 5, 15, and 30, respectively.

If the two examiners disagree as to the seriousness of a problem, then the penalty for the *least* serious call is used. For instance, if the first and second examiners made calls of DEF and ACC for Blood Pressure, then the 5-point penalty for the ACC call stands.

Pocket Depth Qualification is evaluated by three independent examiners. Candidates select 3 teeth they believe satisfy the requirements. Three examiners independently make their calls as to whether these teeth are satisfactory. There is a 10-point deduction off the candidate's total score if two or three examiners agree that the teeth the candidate nominated do not satisfy the requirements; and 20 points are deducted if two or three examiners agree that two or three of the nominated teeth do not satisfy the requirements.

Penalty points do not accumulate across the five case acceptance criteria. Only the *largest* deduction for any of the five criteria is applied. For example, there is a total deduction of 20 points even if a candidate would otherwise lose 10 points for Blood Pressure, 5 points for Radiographs, and 20 points for Pocket Depth Qualification.

Other Point Deductions and Disqualifications

Candidates lose 3 points for each corroborated calculation detection or removal error, such as by saying a surface is calculus free when two or three examiners say it is not free of calculus. Candidates fail the exam if they make: (a) 4 or more corroborated calculus detection errors, (b) 4 or more corroborated calculus removal errors, or (c) a corroborated hard or soft tissue critical error. Candidates lose 1.5 points for each corroborated pocket depth measurement error and 1 point for each plaque and stain removal error.

For additional info on ADEX contact:

ADEXOFFICE@aol.com

(503) 724-1104

ADEX
American Board of Dental Examiners, Inc.
P.O. Box 8733
Portland, OR 97207-8733
Telephone (503) 724-1104
ADEXOFFICE@aol.com
www.adex.org

DENTAL HYGIENE COMMITTEE

MINUTES
November 30, 2012

The Oregon Board of Dentistry (OBD) Dental Hygiene Committee met at the office of the Board on Friday, November 30, 2012.

Committee members present: Jill Mason, M.P.H., R.D.H., E.P.P., Chair; Mary Davidson, M.P.H., R.D.H., E.P.P.; Joni D. Young, D.M.D., ODA Representative; and Kristen L. Simmons, R.D.H., M.H.A., ODHA Representative. The staff present included Patrick Braatz, Executive Director; Lori Lindley, Senior Assistant Attorney General; Stephen Prisby, Office Manager and Teresa Haynes, Licensing Manager.

Visitors present were Beryl Fletcher, ODA; Lisa J. Rowley, R.D.H., Pacific University; Lynn Ironside, R.D.H., ODHA; Heidi Jo Grubbs, R.D.H., ODHA; Jonalee Potter, R.D.H., Oral Health Outreach; Josette Beach, R.D.H., Portland Community College and Vickie Woodward, R.D.H., ODHA.

Board Members Present: Patricia Parker, D.M.D.

Ms. Mason called the meeting to order at 1:30 p.m.

Ms. Davidson moved and Ms. Simmons seconded that the minutes of the July 20, 2012 Dental Hygiene Committee meeting be approved as presented. All members voted in favor.

Mr. Braatz updated the Committee regarding the workgroup meeting held on November 1st with a few of the Program Directors of CODA accredited dental hygiene and dental assisting programs. Based on that workgroup meeting, proposed language was drafted to define "Dentist of Record" in an academic setting pursuant to ORS 679.020(4)(h). Mr. Braatz emailed the proposed language, "For purposes of ORS 679.020(4)(h) the term "dentist of record" means a dentist that is either currently authorizing treatment for or is treating the patient" to the directors and is awaiting their consensus on the wording.

The Committee discussed the possibility of updating the Jurisprudence Examination. Mr. Braatz stated that we are aware that the examination needs to be updated but we have not had time to be able to convene a work group. Mr. Braatz stated that updating the Jurisprudence Examination is on the horizon, but the Board's number one priority is resolving the 218 open complaints.

Ms. Simmons moved and Ms. Davidson seconded to recommend to the Board that they appoint a task force to review the Jurisprudence Examination for possible revision. All members voted in favor.

Mr. Braatz updated the Committee that as of November 29, 2012 there were 313 dental hygienists with an Expanded Practice Permit, and 22 of those hygienists have a collaborative agreement with a dentist.

The Committee reviewed and discussed the nitrous oxide permit application. Ms. Mason, Ms. Rawley and Ms. Beach stated that students at their individual programs are confused on completing the application because when they complete the form they are currently not practicing and the application is asking what their protocols are for administering nitrous oxide.

Ms. Simmons moved and Ms. Davidson seconded to recommend that the Board review the nitrous oxide permit application for possible revision. All members voted in favor.

DRAFT

The Committee established the 2013 Dental Hygiene Committee Dates as follows:

February 1, 2013
June 7, 2013
October 4, 2013
December 6, 2013

There being no further business, the meeting adjourned at 2:01 p.m.

DRAFT

EXECUTIVE DIRECTORS REPORT

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EXECUTIVE DIRECTOR'S REPORT
December 14, 2012

OBD Budget Status Report

Attached is the latest budget report for the 2011-2013 Biennium. This report, which is from July 1, 2011 through October 31, 2012, shows revenue of $1,733,866.90 and expenditures of $1,455,657.74. Revenues continue to be on target and the expenditures to date are actually below what was budgeted. I would say the Budget appears to be performing as expected.

If Board members have questions on this budget report format, please feel free to ask me.
Attachment #1

OBD 2013 - 2015 Governor's Recommended Budget

Attached please find the 2013 – 2015 Governor's Recommended Budget. The Governor made the following proposed cuts to the OBD Agency Budget Request that we submitted to the Department of Administrative Services. The OBD Agency Budget Request was $2,667,844.00 the Governor's Recommended Budget is $2,614,968 a reduction of $52,876. The following are the reductions. Reduction in the base budget of $5,450.00; reduction in Non-Pics Personal Services $1.00; reduction in Standard Inflation Supplies and Services $$13,380.00; reduction Statewide Administrative Savings $4,316.00; reduction PERS Taxation Policy $3,303.00; and reduction PERS Adjustments $26,426.00. **Attachment #2**

Customer Service Survey

Attached is a chart which shows the OBD State Legislatively Mandated Customer Service Survey Results from July 1, 2012 through September 30, 2012.

The results of the survey show that the OBD continues to receive positive comments from the majority of those that return the surveys. The booklet containing the written comments that are on the survey forms, which staff has reviewed, are available on the table for Board members to review. **Attachment #3**

Board and Staff Speaking Engagements

Dental Director/Chief Investigator Dr. Paul Kleinstub, and Licensing Manager Teresa Haynes made a presentation to the Oregon Dental Hygienists' Association Fall Conference in Salem on Friday, October 26, 2012.

Licensing Manager Teresa Haynes and I made a presentation to the graduating Dental Hygiene students at Carrington College on Tuesday, November 6, 2012 in Portland.

Dental Director/Chief Investigator Dr. Paul Kleinstub, and I made a presentation as a part of the DBIC Risk Management Program to the Washington County Dental Society on Tuesday, November 13, 2012 in Beaverton.

I made a presentation as a part of the DBIC Risk Management Program to the MYP Dental Society on Friday, December 7, 2012 in Salem.

HPSP Satisfaction Report

Please find the 3rd Annual HPSP Satisfaction Report. Mr. Wayson and I will be happy to answer questions that you might have regarding this report. **Attachment #4**

Prescription Drug Dispensing In Oregon Report

Please find the first report as a result of the Prescription Monitoring Program in Oregon.
Attachment #5

Newsletter

We have started work on the next issue and have a targeted published date at the end of January.

BOARD OF DENTISTRY
Fund 3400 BOARD OF DENTISTRY
For the Month of OCTOBER 2012

REVENUES

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
0205	OTHER BUSINESS LICENSES	19,831.80	1,618,365.06	2,327,200.00	708,834.94	101,147.82	88,604.37
0210	OTHER NONBUSINESS LICENSES AND FEES	100.00	11,650.00	40,000.00	28,350.00	728.13	3,543.75
0410	CHARGES FOR SERVICES	0.00	0.00	5,000.00	5,000.00	0.00	625.00
0505	FINES AND FORFEITS	0.00	82,758.14	50,000.00	-32,758.14	5,172.38	-4,094.77
0605	INTEREST AND INVESTMENTS	403.61	5,191.34	10,000.00	4,808.66	324.46	601.08
0975	OTHER REVENUE	760.00	15,902.36	25,000.00	9,097.64	993.90	1,137.21
		21,095.41	***1,733,866.90***	***2,457,200.00***	***723,333.10***	***108,366.68***	***90,416.64***

TRANSFER OUT

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
2100	TRANSFER OUT TO DEPT OF HUMAN SERVICES	0.00	0.00	0.00	0.00	0.00	0.00
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	0.00	102,255.00	208,000.00	105,745.00	6,390.94	13,218.13
		0.00	***102,255.00***	***208,000.00***	***105,745.00***	***6,390.94***	***13,218.13***

PERSONAL SERVICES

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
3110	CLASS/UNCLASS SALARY & PER DIEM	35,297.47	556,504.87	855,336.00	298,831.13	34,781.55	37,353.89
3160	TEMPORARY APPOINTMENTS	0.00	14,107.23	3,717.00	-10,390.23	881.70	-1,298.78
3170	OVERTIME PAYMENTS	458.50	10,183.71	3,575.00	-6,608.71	636.48	-826.09
3210	ERB ASSESSMENT	8.50	125.80	287.00	161.20	7.86	20.15
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	4,662.85	79,335.19	123,464.00	44,128.81	4,958.45	5,516.10
3221	PENSION BOND CONTRIBUTION	1,914.09	32,047.42	49,432.00	17,384.58	2,002.96	2,173.07
3230	SOCIAL SECURITY TAX	2,685.06	44,171.86	71,160.00	26,988.14	2,760.74	3,373.52
3250	WORKERS' COMPENSATION ASSESSMENT	17.21	255.66	413.00	157.34	15.98	19.67
3260	MASS TRANSIT	199.03	3,238.96	5,581.00	2,342.04	202.44	292.76
3270	FLEXIBLE BENEFITS	7,803.40	122,446.79	201,638.00	79,191.21	7,652.92	9,898.90
		53,046.11	***862,417.49***	***1,314,603.00***	***452,185.51***	***53,901.09***	***56,523.19***

SERVICES and SUPPLIES

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
4100	INSTATE TRAVEL	2,263.83	33,824.26	46,655.00	12,830.74	2,114.02	1,603.84

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
4125	OUT-OF-STATE TRAVEL	4,830.92	18,665.35	24,672.00	6,006.65	1,166.58	750.83
4150	EMPLOYEE TRAINING	0.00	6,255.00	6,617.00	362.00	390.94	45.25
4175	OFFICE EXPENSES	7,964.39	53,483.15	78,445.00	24,961.85	3,342.70	3,120.23
4200	TELECOMM/TECH SVC AND SUPPLIES	30.42	15,195.55	25,757.00	10,561.45	949.72	1,320.18
4225	STATE GOVERNMENT SERVICE CHARGES	40.50	64,418.95	78,170.00	13,751.05	4,026.18	1,718.88
4250	DATA PROCESSING	181.75	2,945.50	5,400.00	2,454.50	184.09	306.81
4275	PUBLICITY & PUBLICATIONS	533.38	10,819.68	13,084.00	2,264.32	676.23	283.04
4300	PROFESSIONAL SERVICES	3,453.80	60,362.05	79,219.00	18,856.95	3,772.63	2,357.12
4315	IT PROFESSIONAL SERVICES	0.00	12,700.00	50,000.00	37,300.00	793.75	4,662.50
4325	ATTORNEY GENERAL LEGAL FEES	3,492.20	108,052.48	188,592.00	80,539.52	6,753.28	10,067.44
4375	EMPLOYEE RECRUITMENT AND	0.00	0.00	621.00	621.00	0.00	77.63
4400	DUES AND SUBSCRIPTIONS	0.00	8,895.90	8,276.00	-619.90	555.99	-77.49
4425	FACILITIES RENT & TAXES	6,409.53	91,845.17	139,571.00	47,725.83	5,740.32	5,965.73
4475	FACILITIES MAINTENANCE	0.00	0.00	514.00	514.00	0.00	64.25
4575	AGENCY PROGRAM RELATED SVCS & SUPP	1,071.50	78,511.00	164,976.00	86,465.00	4,906.94	10,808.13
4650	OTHER SERVICES AND SUPPLIES	685.80	27,013.18	40,300.00	13,286.82	1,688.32	1,660.85
4700	EXPENDABLE PROPERTY $250-$5000	0.00	0.00	5,140.00	5,140.00	0.00	642.50
4715	IT EXPENDABLE PROPERTY	0.00	253.03	5,140.00	4,886.97	15.81	610.87
		30,958.02	***593,240.25***	***961,149.00***	***367,908.75***	***37,077.52***	***45,988.59***

SPECIAL PAYMENTS

Budget Obj	Budget Obj Title	Monthly Activity	Biennium to Date Activity	Financial Plan	Unobligated Plan	Monthly Avg to Date	Monthly Avg to Spend
6100	DISTRIBUTION TO DEPT OF HUMAN	0.00	0.00	0.00	0.00	0.00	0.00
6443	DIST TO OREGON HEALTH AUTHORITY	0.00	66,666.00	226,292.00	159,626.00	4,166.63	19,953.25
		0.00	***66,666.00***	***226,292.00***	***159,626.00***	***4,166.63***	***19,953.25***

SUMMARY TOTALS

3400

BOARD OF DENTISTRY

		Month Activity	Biennium Activity
REVENUES	REVENUE	21,095.41	1,733,866.90
	Total	21,095.41	1,733,866.90
EXPENDITURES	PERSONAL SERVICES	53,046.11	862,417.49
	SERVICES AND SUPPLIES	30,958.02	593,240.25
	Total	84,004.13	1,455,657.74
TRANSFER OUT	TRANSFER OUT	0.00	102,255.00
	Total	0.00	102,255.00
SPECIAL PAYMENTS	SPECIAL PAYMENTS	0.00	66,666.00

	3400	
	BOARD OF DENTISTRY	
	Month Activity	Biennium Activity
Total	0.00	66,666.00

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Governor's 2013-15 Balanced Budget

Oregonians have clear priorities when it comes to state spending – invest in children and education first; focus on job creation and innovation; and reduce the cost of government. The Governor's recommended balanced budget for the 2013-15 biennium delivers on those priorities.

First and foremost, the Governor's balanced budget is an education investment budget. It is based on the premise that we must deliver better results for students and better prepare our workforce for the new economy to rebuild the a strong, secure middle class and restore our shared prosperity.

EDUCATION – Putting children, families, and education first with:

- **$8 Billion for education**, reversing the trend of cuts and layoffs and investing in pre-school to K-12 to college and career.
- **A $55 million increase for child safety programs** such as relief nurseries, child protective services and community mental health to improve the health and welfare of children.
- **Realignment of early learning programs** including childcare, health care and pre-school services, to ensure all children are ready to learn when they get to kindergarten.
- **More teachers and school days for K-12** with $6.15 billion, *plus $253 million in PERS savings,* to begin to reinvest in K-12 education, enough to hire an additional 500 teachers.
- **This is the first time since 2007** that the K-12 budget has been above Current Service Levels, excluding one-time federal dollars.
- **Expanding access to post-secondary education and training** for all Oregonians by increasing funding for Opportunity Grants to $113.4 million, providing more options for high school students to accrue college credit early and supporting tuition equity to ensure every qualified Oregon high school graduate, regardless of immigration status, has access to affordable higher education.

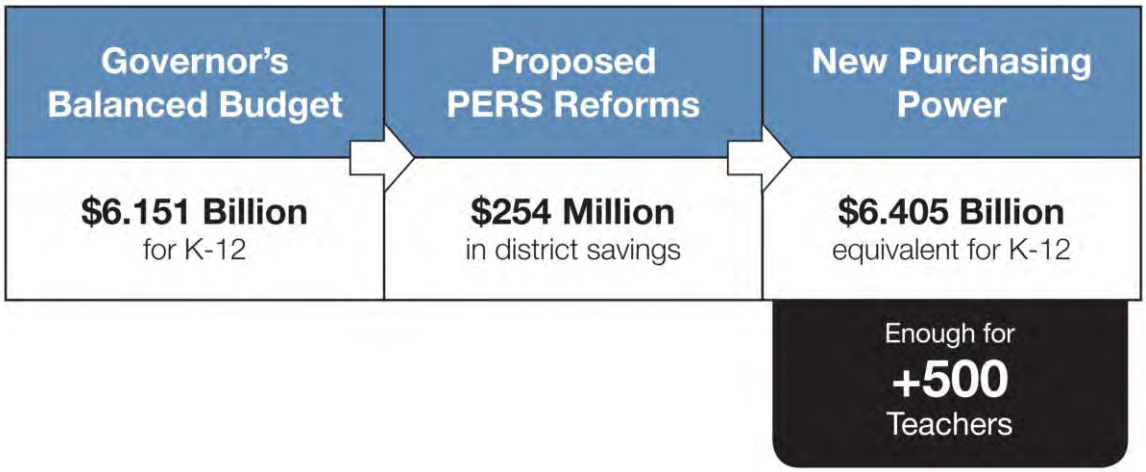
JOBS – Investing in jobs and innovation with:

- **Over $1 Billion for Core Infrastructure Projects** with funding for the Interstate 5 bridge replacement, water projects, university buildings, airport, marine and rail improvements, seismic upgrades, and technology infrastructure projects that get Oregonians back to work. A robust infrastructure system is a crucial component underlying regional competitiveness, business attraction and retention and job creation.

- **$90 million for proven partnerships** that bring together leaders from private business and the state's research universities to develop the state's innovation strategy. Partnerships include the Oregon Innovation Council, Oregon's Signature Research Centers, and University-based innovation, agriculture and forestry research initiatives.
- **$10 million for workforce development** to better align programs with employer needs. These initiatives will assure that more Oregonians have the foundational and problem solving skills to compete for jobs in growing businesses and are able to gain industry specific training.
- **Regulatory Reforms** to remove barriers to private investment and job creation.
- **A more than 30 percent increase to the Earned Income Tax Credit** and funding for Employment Related Day Care to help working families keep more of what they earn and move up the income ladder.

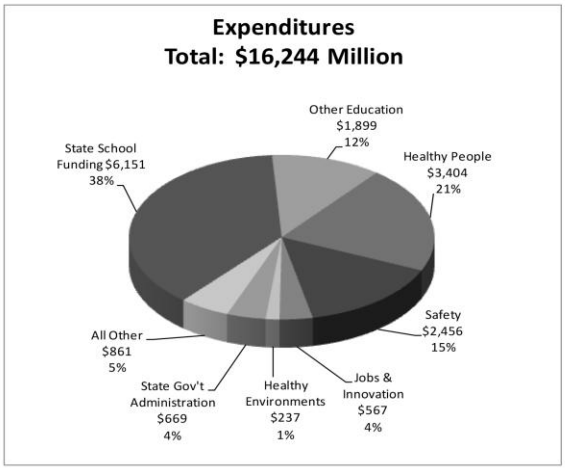
COSTS – Lowering Costs:

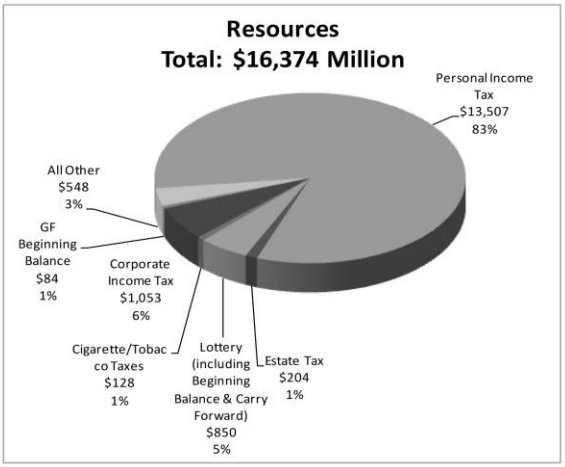
- **$865 million in PERS savings system-wide** from adjusting out-of-state benefits and capping cost-of-living increases. More than half of retirees will see no change to their retirement benefits.
- **$11 billion in expected health care savings** over the next decade by Implementing health care reforms for better care at lower cost.
- **$600 million in avoided prison costs** over the next decade through public safety reforms and local investment in proven prevention and community corrections strategies.



BUDGET BASICS:

- The Governor's balanced budget for 2013-2015 is $60.2 billion in total funds – about 2.3 percent larger than the current 2011-13 budget. This includes $16.4 billion of combined General Fund/Lottery Funds, which is about 9.9% higher than the current 2011-13-budget.
- This budget furthers many of the reforms the Governor has pursued since taking office, including reducing the cost of health care, improving care, realigning state programs to improve early childhood services, and directing cost savings back into the classroom to help the state meet its ambitious education goals.
- By the end of the 2013-15 biennium, the Governor's balanced budget shows $250 million in the Rainy Day Fund and another $186 million in the Education Stability Fund – or about $436 million total in reserves.





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Summary of 2013-15 Tentative Budget
Board of Dentistry

	A	B	C	D	E	G	H	I	J	K	L
4			TOTALS			FUND TYPE					
5			POS	FTE	ALL	General	Lottery	Other	Federal	Nonlimited	
6					FUNDS	Fund	Funds	Funds	Funds	Other	Federal
8	**2011-13 Legislatively Approved Budget**										
9		Personal Services	7	7.00	1,314,603	0	0	1,314,603	0	0	0
10		Services & Supplies			961,149	0	0	961,149	0	0	0
11		Capital Outlay			0	0	0	0	0	0	0
12		Special Payments			226,292	0	0	226,292	0	0	0
13		Debt Service			0	0	0	0	0	0	0
15	**2011-13 Legislatively Approved Budget**		**7**	**7.00**	**2,502,044**	**0**	**0**	**2,502,044**	**0**	**0**	**0**
60											
61		Change to LAB	0%	0%	7%			7%			
62											
63	**2013-15 CSL**										
64		Personal Services	7	7.00	1,409,562	0	0	1,409,562	0	0	0
65		Services & Supplies			1,028,066	0	0	1,028,066	0	0	0
66		Capital Outlay			0	0	0	0	0	0	0
67		Special Payments			230,216	0	0	230,216	0	0	0
68		Debt Service			0	0	0	0	0	0	0
69		**Subtotal**	**7**	**7.00**	**2,667,844**	**0**	**0**	**2,667,844**	**0**	**0**	**0**
70											
71											
72	**Package xxx:**										
73		Personal Services									
74		Services & Supplies									
75		Capital Outlay									
76		Special Payments									
77		Debt Service									
78		**Total package**									
79											
80	**Package xxx:**										
81		Personal Services									
82		Services & Supplies									
83		Capital Outlay									
84		Special Payments									
85		Debt Service									
86		**Total package**									
87											
88											
89											
90	**2013-15 ARB**										
91		Personal Services	7	7.00	1,409,562	0	0	1,409,562	0	0	0
92		Services & Supplies			1,028,066	0	0	1,028,066	0	0	0
93		Capital Outlay			0	0	0	0	0	0	0
94		Special Payments			230,216	0	0	230,216	0	0	0
95		Debt Service			0	0	0	0	0	0	0
96		**Subtotal**	**7**	**7.00**	**2,667,844**	**0**	**0**	**2,667,844**	**0**	**0**	**0**
97											

	A	B	C	D	E	G	H	I	J	K	L
98											
99	**Package 000: Base adj**										
100		Personal Services	0	0.00				-5,450			
101		Services & Supplies									
102		Capital Outlay									
103		Special Payments									
104		Debt Service									
105		**Total package**	0	0.00	-5,450	0	0	-5,450	0	0	0
106											
107	**Package 010: Ess pkgs, non-PICS PS**										
108		Personal Services	0	0.00				-1			
109		Services & Supplies									
110		Capital Outlay									
111		Special Payments									
112		Debt Service									
113		**Total package**	0	0.00	-1	0	0	-1	0	0	0
114											
115	**Package 031: Standard inflation and SGSC**										
116		Personal Services	0	0.00							
117		Services & Supplies						-13,380			
118		Capital Outlay									
119		Special Payments									
120		Debt Service									
121		**Total package**	0	0.00	-13,380	0	0	-13,380	0	0	0
122											
123	**Package 091: Statewide admin savings**										
124		Personal Services	0	0.00				-2,496			
125		Services & Supplies						-1,820			
126		Capital Outlay									
127		Special Payments									
128		Debt Service									
129		**Total package**	0	0.00	-4,316	0	0	-4,316	0	0	0
130											
131	**Package 092: PERS taxation policy**										
132		Personal Services	0	0.00				-3,303			
133		Services & Supplies									
134		Capital Outlay									
135		Special Payments									
136		Debt Service									
137		**Total package**	0	0.00	-3,303	0	0	-3,303	0	0	0
138											
139	**Package 093: Other PERS adjs**										
140		Personal Services	0	0.00		0		-26,426			
141		Services & Supplies									
142		Capital Outlay									
143		Special Payments									
144		Debt Service									
145		**Total package**	0	0.00	-26,426	0	0	-26,426	0	0	0
146											
147											

	A	B	C	D	E	G	H	I	J	K	L
148											
149											
150		**2013-15 GRB**									
151		Personal Services	7	7.00	1,371,886	0	0	1,371,886	0	0	0
152		Services & Supplies			1,012,866	0	0	1,012,866	0	0	0
153		Capital Outlay			0	0	0	0	0	0	0
154		Special Payments			230,216	0	0	230,216	0	0	0
155		Debt Service			0	0	0	0	0	0	0
156		**Subtotal**	**7**	**7.00**	**2,614,968**	**0**	**0**	**2,614,968**	**0**	**0**	**0**
157											
158		Percent change vs. LAB	0%	0%	5%			5%			
159											
160											
161											
162											
163		**Package 091 calcs:**									
164		Reduction total			-4,316			-4,316			
165		Personal Services						-2,496			
166		Services & Supplies						-1,820			
167		Capital Outlay									
168		Special Payments									
169		Debt Service									
170						0	0	-4,316	0	0	0
171											
172											
173		**PERS 092 calcs:**									
174		General services	(0.0210)								
175		Total acct 3220 PERS + adjs						157,480			
176											
177		Personal Services				0	0	-3,303	0	0	0
178		Services & Supplies									
179		Capital Outlay									
180		Special Payments									
181		Debt Service									
182											
183		**PERS 093 calcs:**									
184		General services	(0.1678)								
185		Total acct 3220 PERS				0	0	157,480	0	0	0
186											
187		Personal Services				0	0	-26,426	0	0	0
188		Services & Supplies									
189		Capital Outlay									
190		Special Payments									
191		Debt Service									
192											
193											
194		**ORBITS**									
195		Pkg 031									
196		GF approp									
197		Adj GF approp				0					
198											
199											
200		**Pkg 031**									
201		OAH						-2,910			
202		SGSC						-10,470			
203		Total						-13,380			
204											

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	N	O	P	Q	R	S
1	2015-17 Biennium					
2						
4	FUND TYPE					
5	General	Lottery	Other	Federal	Nonlimited	
6	Fund	Funds	Funds	Funds	Other	Federal
8						
9	0	0	1,678,616	0	0	0
10	0	0	1,010,791	0	0	0
11	0	0	0	0	0	0
12	0	0	237,980	0	0	0
13	0	0	0	0	0	0
15	**0**	**0**	**2,927,387**	**0**	**0**	**0**
60						
61						
62						
63						
64	0	0	0	0	0	0
65	0	0	0	0	0	0
66	0	0	0	0	0	0
67	0	0	0	0	0	0
68	0	0	0	0	0	0
69	**0**	**0**	**0**	**0**	**0**	**0**
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90						
91	0	0	1,678,616	0	0	0
92	0	0	1,010,791	0	0	0
93	0	0	0	0	0	0
94	0	0	237,980	0	0	0
95	0	0	0	0	0	0
96	**0**	**0**	**2,927,387**	**0**	**0**	**0**
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149						
150						
151	0	0	1,678,616	0	0	0
152	0	0	1,010,791	0	0	0
153	0	0	0	0	0	0
154	0	0	237,980	0	0	0
155	0	0	-5,451	0	0	0
156	**0**	**0**	**2,921,936**	**0**	**0**	**0**
157						

	U	V	W	X	Y	Z
1	2017-19 Biennium					
2						
4	FUND TYPE					
5	General	Lottery	Other	Federal	Nonlimited	
6	Fund	Funds	Funds	Funds	Other	Federal
8						
9	0	0	1,896,836	0	0	0
10	0	0	1,037,072	0	0	0
11	0	0	0	0	0	0
12	0	0	244,167	0	0	0
13	0	0	0	0	0	0
15	**0**	**0**	**3,178,075**	**0**	**0**	**0**
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64	0	0	0	0	0	0
65	0	0	0	0	0	0
66	0	0	0	0	0	0
67	0	0	0	0	0	0
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69	**0**	**0**	**0**	**0**	**0**	**0**
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91	0	0	1,896,836	0	0	0
92	0	0	1,037,072	0	0	0
93	0	0	0	0	0	0
94	0	0	244,167	0	0	0
95	0	0	0	0	0	0
96	**0**	**0**	**3,178,075**	**0**	**0**	**0**
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151	0	0	1,896,836	0	0	0
152	0	0	1,037,072	0	0	0
153	0	0	0	0	0	0
154	0	0	244,167	0	0	0
155	0	0	0	0	0	0
156	**0**	**0**	**3,178,075**	**0**	**0**	**0**
157						

	AB	AC	AD	AE	AF	AG
1	2019-21 Biennium					
2						
4	FUND TYPE					
5	General	Lottery	Other	Federal	Nonlimited	
6	Fund	Funds	Funds	Funds	Other	Federal
8						
9	0	0	2,143,425	0	0	0
10	0	0	1,061,962	0	0	0
11	0	0	0	0	0	0
12	0	0	250,027	0	0	0
13	0	0	0	0	0	0
15	**0**	**0**	**3,455,414**	**0**	**0**	**0**
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64	0	0	0	0	0	0
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66	0	0	0	0	0	0
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68	0	0	0	0	0	0
69	**0**	**0**	**0**	**0**	**0**	**0**
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91	0	0	2,143,425	0	0	0
92	0	0	1,061,962	0	0	0
93	0	0	0	0	0	0
94	0	0	250,027	0	0	0
95	0	0	0	0	0	0
96	**0**	**0**	**3,455,414**	**0**	**0**	**0**
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151	0	0	2,143,425	0	0	0
152	0	0	1,061,962	0	0	0
153	0	0	0	0	0	0
154	0	0	250,027	0	0	0
155	0	0	0	0	0	0
156	**0**	**0**	**3,455,414**	**0**	**0**	**0**
157						

	AI	AJ	AK	AL	AM	AN
1	2021-23 Biennium					
2						
4	FUND TYPE					
5	General	Lottery	Other	Federal	Nonlimited	
6	Fund	Funds	Funds	Funds	Other	Federal
8						
9	0	0	2,422,070	0	0	0
10	0	0	1,087,449	0	0	0
11	0	0	0	0	0	0
12	0	0	256,028	0	0	0
13	0	0	0	0	0	0
15	**0**	**0**	**3,765,547**	**0**	**0**	**0**
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69	**0**	**0**	**0**	**0**	**0**	**0**
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91	0	0	2,422,070	0	0	0
92	0	0	1,087,449	0	0	0
93	0	0	0	0	0	0
94	0	0	256,028	0	0	0
95	0	0	0	0	0	0
96	**0**	**0**	**3,765,547**	**0**	**0**	**0**
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	AI	AJ	AK	AL	AM	AN
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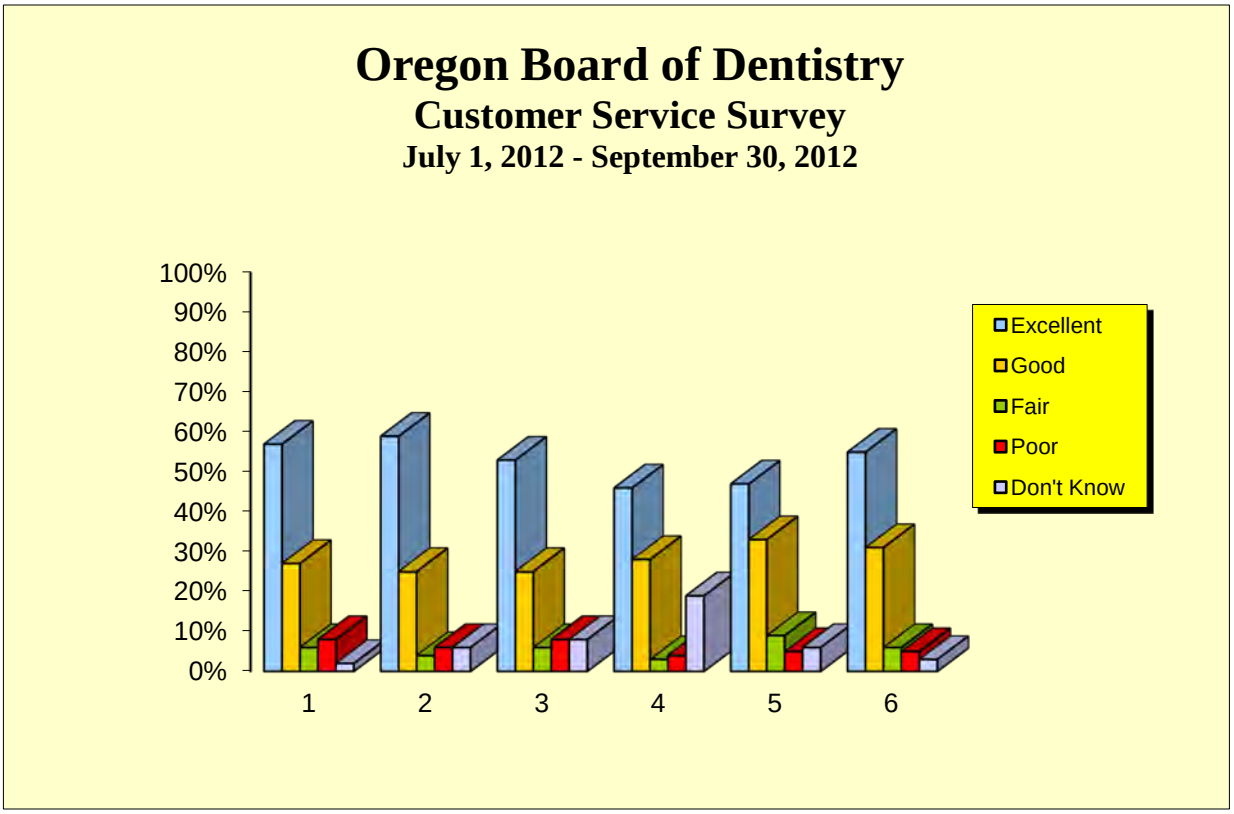
151	0	0	2,422,070	0	0	0
152	0	0	1,087,449	0	0	0
153	0	0	0	0	0	0
154	0	0	256,028	0	0	0
155	0	0	0	0	0	0
156	**0**	**0**	**3,765,547**	**0**	**0**	**0**
157						



1 How do you rate the timeliness of the services provided by the OBD?
E= 57% G= 27% F= 6% P= 8% DK= 2%

2 How do you rate the ability of the OBD to provide services correctly the first time?
E= 59% G= 25% F= 4% P= 6% DK= 6%

3 How do you rate the helpfulness of the OBD?
E= 53% G= 25% F= 6% P= 8% DK= 8%

4 How do you rate the knowledge and expertise of the OBD?
E= 46% G= 28% F= 3% P= 4% DK= 19%

5 How do you rate the availability of information at the OBD?
E= 47% G= 33% F= 9% P= 5% DK= 6%

6 How do you rate the overall quality of services provided by the OBD?
E= 55% G= 31% F= 6% P= 5% DK= 3%

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Reliant Behavioral Health, LLC
Health Professionals' Services Program (HPSP)
Satisfaction Report

Year 3, Quarter 1: July 1, 2012 – September 30, 2012

RBH Health Professionals' Services Program
1220 SW Morrison Street, Suite 600
Portland, Oregon 97205
1.888.802.2843
Fax: 503.961.7142

Executive Summary

Health Professionals' Services Program Satisfaction Survey: Year Three, Quarter 1

Overview: This Health Professionals' Services Program report reviews the survey results from the first quarter of the third year of the program, covering July 1, 2012 through September 30, 2012. Surveys were sent only to the Licensees this quarter; all of the groups of stakeholders will be surveyed again in January 2013.

An overview of the number of surveys sent, number of responses received, and the response rate for each group of stakeholders in October is displayed below:

Table 1: Response Rate - October 2012	Licensees	Employers (Workplace Monitors)	Treatment Programs	Health Associations	Acumentra	Boards
# Sent	314	N/A	N/A	N/A	N/A	N/A
# of Responses	81	N/A	N/A	N/A	N/A	N/A
Response Rate	25.8%	N/A	N/A	N/A	N/A	N/A

Highlights: This is the first quarter report for year 3. As I reviewed this report and compared it to last quarter and the final report of year two, I noticed that the reports are very similar. We had 81 respondents this quarter which is a slight decrease from 84 from last quarter. We continue to have a good return rate on the survey with a response rate of 25.8% as 314 surveys were sent out. Interestingly this was the first quarter where there was a disproportionate return rate between the number of licensees in the program and the number of respondents enrolled in the program. Specifically, 46% of the respondents are from the OMB and they represent only 32% of the enrollees. The OSBN represents 41% of the respondents but 56% of the enrollees. For greater detail, please see Respondents by Board.

Overall the responses to the program were positive with only a slight decrease in Customer Service, that information was communicated concisely and clearly. The rating this quarter was 69.1% and for year two it was 76.6%. Otherwise this survey approximates last quarter fairly closely. This is particularly true for how the licensees rated the value of their agreement monitors, toxicology testing, newsletter and website. It is positive that both the website and newsletter were rated positively this quarter. There has been significant work on both tools to improve their value to licensees.

In reviewing the Executive Summary from last quarter, the summary also describes the comments received this quarter. There continues to be a group of licensees that are very dissatisfied with the program. We will review the comments and develop action plans for issues which we have control over.

Reliant Behavioral Health
Health Professionals' Services Program (HPSP)
Satisfaction of LICENSEES

Purpose

The purpose of assessing participants (Licensees) of the Health Professionals' Services Program (HPSP) is to obtain constructive feedback that can be used to improve and maintain the quality, effectiveness, and efficiency of the HPSP Program. In order to provide continuous quality services, RBH evaluates Licensees' satisfaction with the HPSP Program on a quarterly basis.

Feedback is obtained from Licensees via a satisfaction survey that is mailed or emailed to each Licensee. When mailed, Licensees are given the option of completing the enclosed survey and mailing it back to the RBH offices in the postage-paid envelope, or going through the link to the survey and completing it online. The survey is short and can be completed in 2-3 minutes.

Feedback includes information about RBH customer service, Agreement Monitors, service components, and overall services.

The effectiveness of the HPSP Program is measured by using valid methods. The RBH Quality Management Committee (QMC) sets performance goals for each measure. In reviewing the survey results, the QMC will identify opportunities for improvement and develop interventions if necessary. The QMC continues to monitor performance at specified intervals following the implementation of the intervention(s).

Data Results

Response Rate

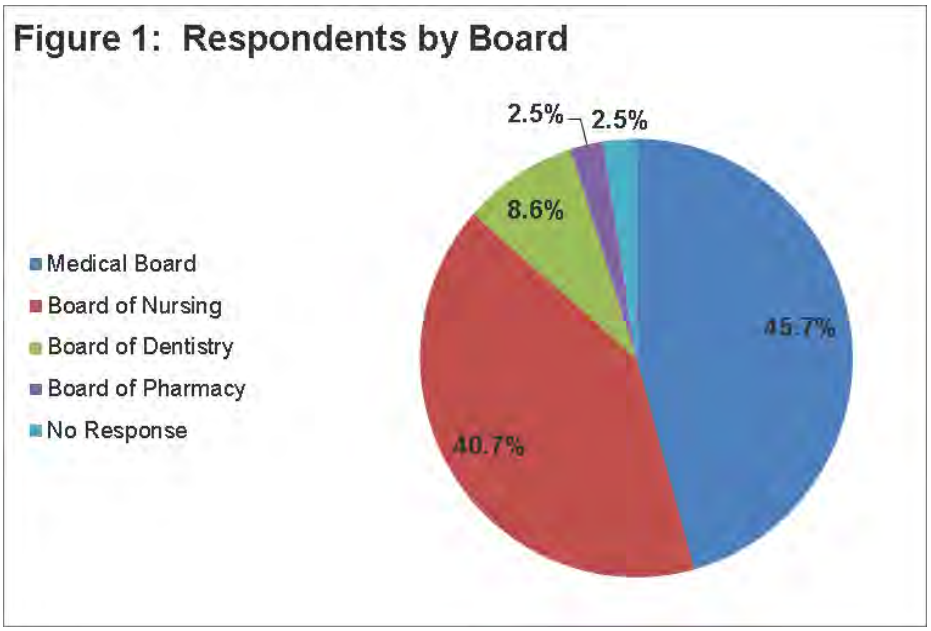
Table 1: Response Rate	This Quarter
# Sent	314
# of Responses	81
Response Rate	25.8%

The HPSP Licensee Satisfaction Survey was issued to 100% of the Licensees enrolled in the HPSP Program at the end of September 2012. The survey was emailed to 256 licensees and mailed to 58. A total of 81 responses were received, representing a response rate of 25.8%. This is down slightly from our average response rate during Year 2, which was 27.6%, but still an increase from Year 1's rate of 23%.

Respondents

45.7% of respondents this quarter were representatives of the Medical Board, followed by the Board of Nursing at 40.7%. The Board of Dentistry was represented by 8.6% of the respondents and the Board of Pharmacy by 2.5%. (See Table 2 and Figure 1)

Table 2: Respondents by Board	This Quarter (n=81)	
	#	%
Medical Board	37	45.7%
Board of Nursing	33	40.7%
Board of Dentistry	7	8.6%
Board of Pharmacy	2	2.5%
No Response	2	2.5%



The breakdown of respondents is compared to the percent of enrollees in the program in Table 3 below. Note that the Medical Board represents 46% of the respondents but only 32% of the enrollees, while the Board of Nursing represents 41% of the respondents but 56% of the enrollees. The other two boards show a similar pattern, although with a smaller change in percentages: The Board of Dentistry represents nearly 9% of the respondents, but only 6% of the enrollees while the Board of Pharmacy represents only 2.5% of the respondents, but 6% of the enrollees. Thus, the responses in this survey are not as representative of each board as we have seen in prior quarters.

Table 3: Comparison of Enrollees to Respondents	Percent of Enrollees in the Program (10/3/12)	Percent of Respondents (This Quarter)
Medical Board	32.3%	45.7%
Board of Nursing	55.9%	40.7%
Board of Dentistry	6.1%	8.6%
Board of Pharmacy	5.8%	2.5%

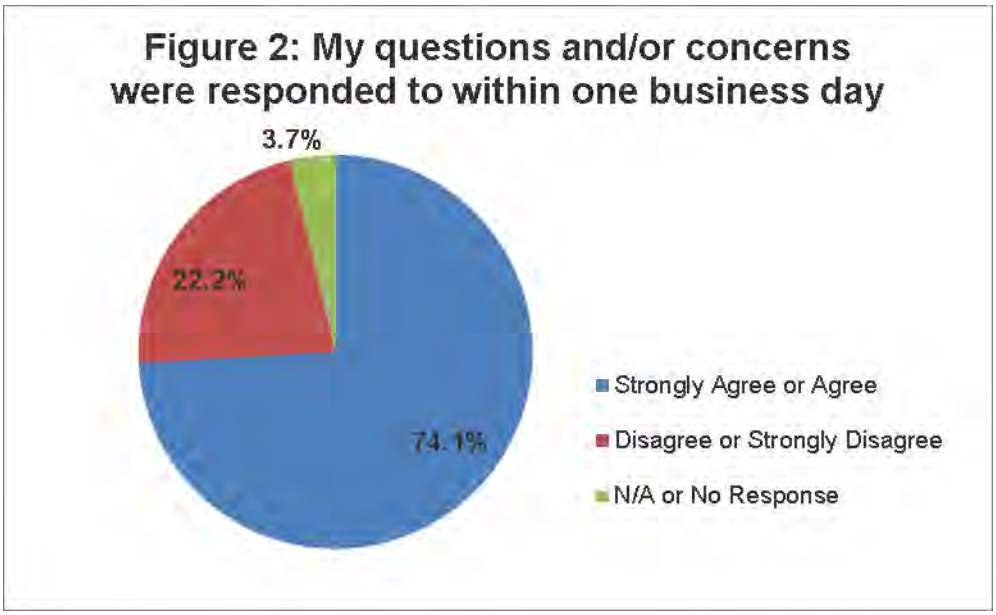
Customer Service

This question asks respondents to "Think about [their] most recent call to RBH……" and evaluate 2 statements. The mode (most frequent) responses are highlighted in red:

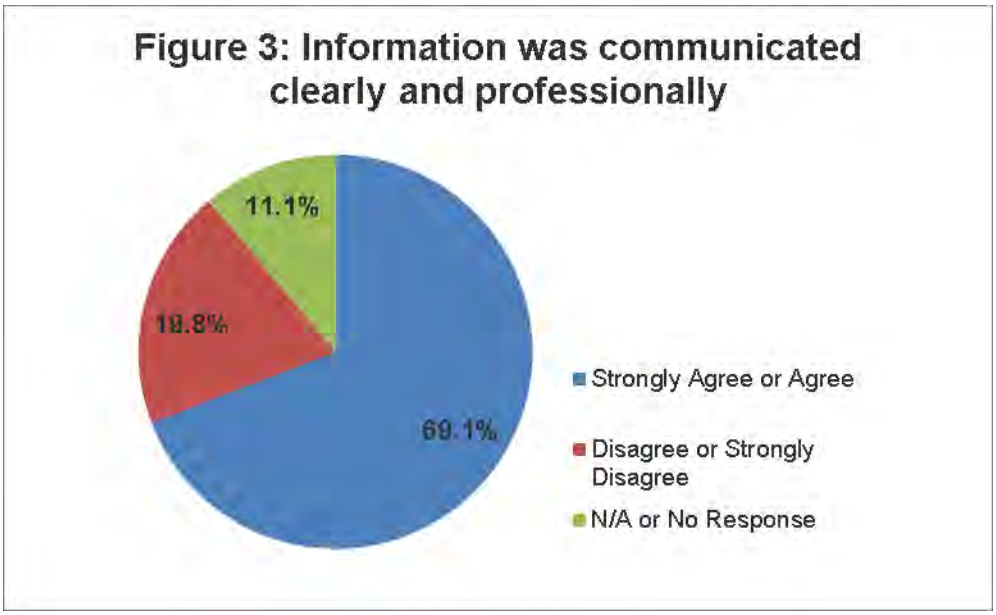
Table 4: This Quarter (n=81)	Strongly Agree		Agree		Disagree		Strongly Disagree		N/A		No Response	
	#	%	#	%	#	%	#	%	#	%	#	%
My Questions and/or Concerns Were Responded to within one business day	34	42.0%	26	32.1%	5	6.2%	13	16.0%	3	3.7%	0	0.0%
Information was Communicated Clearly and Professionally	33	40.7%	23	28.4%	9	11.1%	7	8.6%	3	3.7%	6	7.4%

The largest group of respondents for the quarter indicated that they "strongly agree" that their questions/concerns were responded to within 1 business day and that information was communicated clearly and professionally. For both items, this is an improvement from last year's overall mode response of "Agree."

Combined, 74.1% of respondents indicate that they "Agree" or "Strongly Agree" that their questions and/or concerns were responded to within one business day. Across all of Year 2, 74.9% responded in this way.



Again combined, 69.1% indicate that they agree or strongly agree that information was communicated clearly and professionally (see Figure 3, next page). This is a decrease from the 76.6% combined responses in Year 2. This demonstrates that although this quarter showed an increase in the percentage of respondents who "Strongly Agree" with this item, combined there are less respondents who positively endorsed this item with a response of "Agree" or "Strongly Agree." It appears that there is increased polarization in feelings about the program. This is a trend that will be monitored in future surveys.



Agreement Monitors

The next item asked respondents to react to the following: "Regarding our Agreement Monitors, to what extent do you agree that..." Again, the mode (most frequent) response is in red:

Table 5: This Quarter (n=81)	Strongly Agree		Agree		Disagree		Strongly Disagree		N/A		No Response	
	#	%	#	%	#	%	#	%	#	%	#	%
My Agreement Monitor is knowledgeable about my case	35	43.2%	31	38.3%	8	9.9%	7	8.6%	0	0.0%	0	0.0%
My needs and concerns are understood	35	43.2%	23	28.4%	9	11.1%	12	14.8%	0	0.0%	2	2.5%

The largest group of respondents for the quarter indicated that they "strongly agree" that their Agreement Monitor is knowledgeable about their case and that their needs and concerns are understood. Again for both items, this is an improvement from last year's overall mode response of "Agree."

81.5% of respondents agree or strongly agree that (his/her) Agreement Monitor is knowledgeable about (his/her) case. (See Figure 4 – next page.) This is an improvement from 78.5% last year. Similarly, 71.6% of respondents agree or strongly agree that (his/her) needs and concerns are understood. (See Figure 5 – next page.) This is a slight decrease from 73.6% from last year.

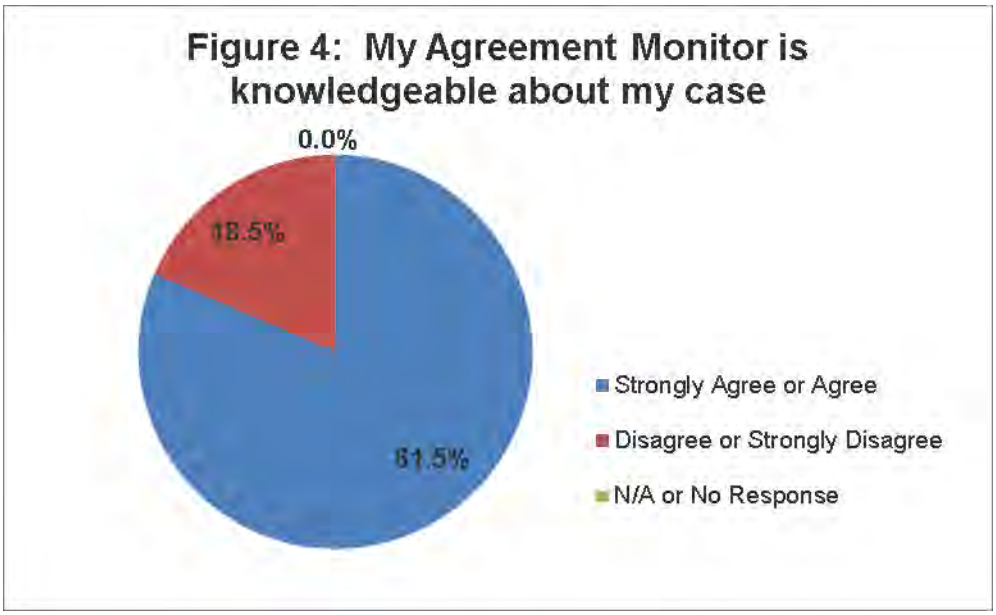


Figure 4: My Agreement Monitor is knowledgeable about my case
0.0%
18.5%
81.5%
Strongly Agree or Agree
Disagree or Strongly Disagree
N/A or No Response

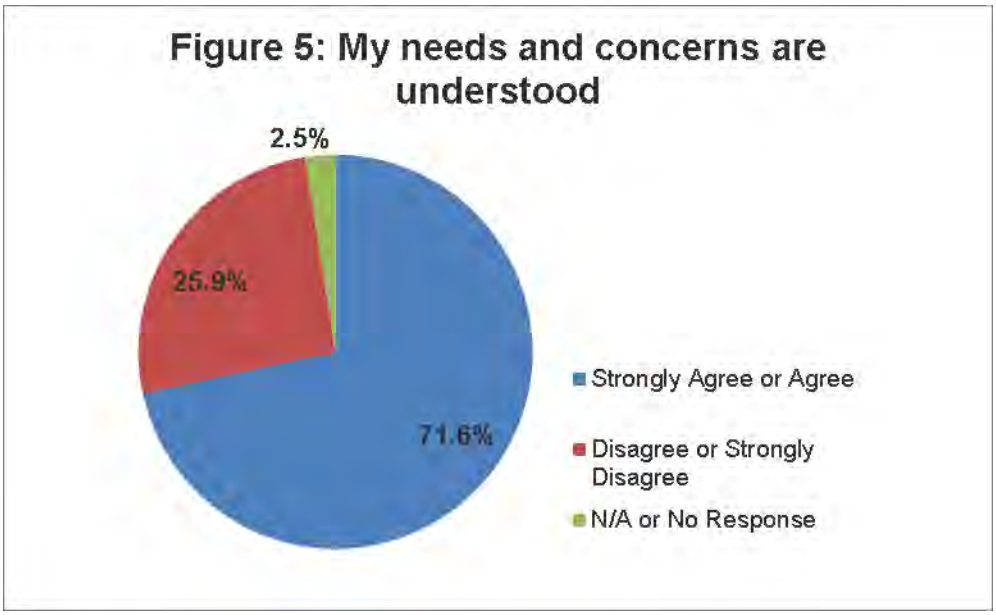


Figure 5: My needs and concerns are understood
2.5%
25.9%
71.6%
Strongly Agree or Agree
Disagree or Strongly Disagree
N/A or No Response

Service Components

This item asked respondents to "Please rate the following services as they contribute to your successful completion of the program." This quarter, two new service components were added ***only*** for OMB licensees to address. Analysis of these items, "Individual Monitoring Consultants" and "Group Monitoring," was limited to the responses from the OMB licensees as well as to those who did not specifiy a board but responded to this question. Thus, the pool for these 2 items is 38 rather than 81.

The mode (most frequent) response is in red.

Table 6: This Quarter (n=81; OMB licensee only questions n=38)	Extremely Helpful		Helpful		Unhelpful		Extremely Unhelpful		No Response	
	#	%	#	%	#	%	#	%	#	%
Agreement Monitor contacts	19	23.5%	32	**39.5%**	19	23.5%	8	9.9%	3	3.7%
Newsletter	7	8.6%	48	**59.3%**	16	19.8%	8	9.9%	2	2.5%
Toxicology testing	11	13.6%	35	**43.2%**	21	25.9%	11	13.6%	3	3.7%
Website	4	4.9%	36	**44.4%**	24	29.6%	12	14.8%	5	6.2%
Individual Monitoring Consultants (OMB licensees)	4	10.5%	15	**39.5%**	7	18.4%	7	18.4%	5	13.2%
Group Monitoring (OMB licensees)	5	13.2%	13	**34.2%**	8	21.1%	6	15.8%	6	15.8%

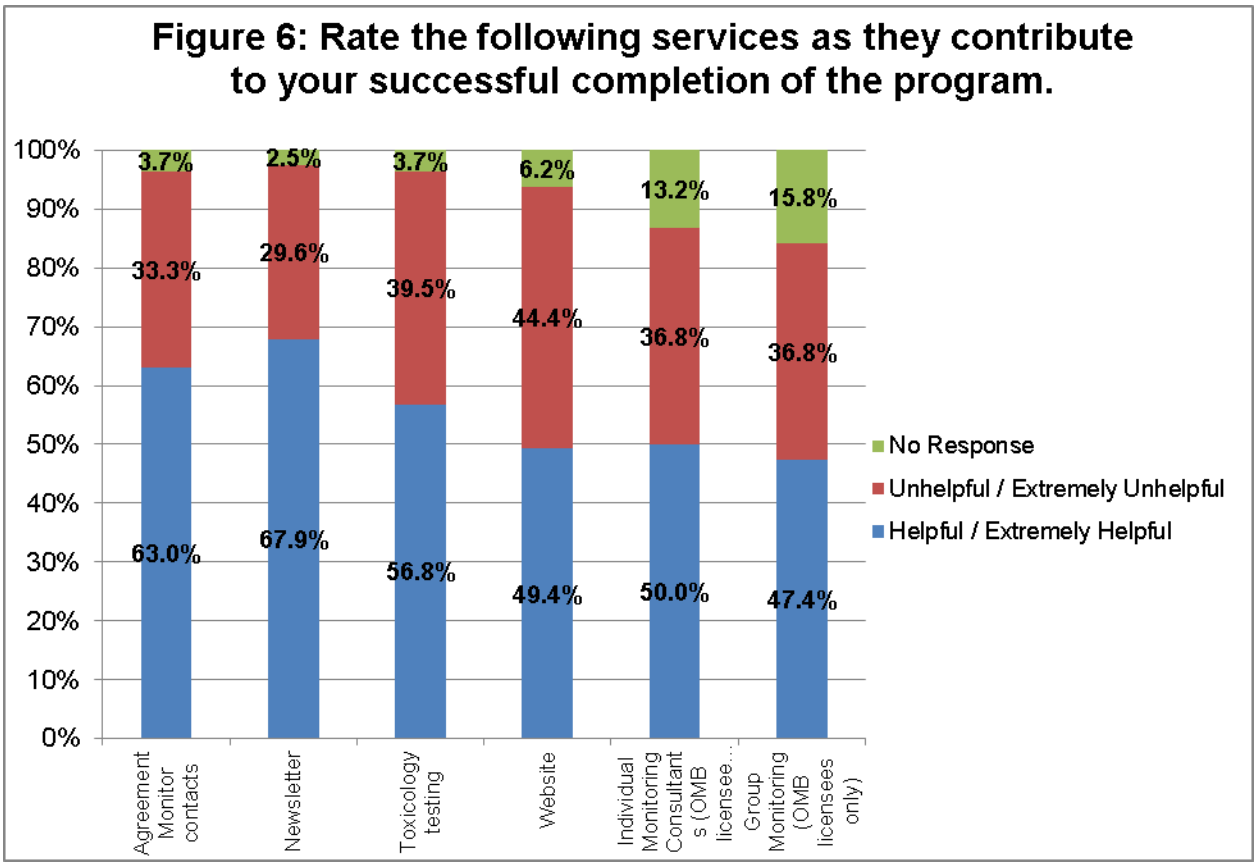
As seen previously, the mode response is "Helpful" for all items. However, the percentage of "Extremely Helpful" responses increased for all items from last quarter:

Services	Extremely Helpful Rating This Quarter	Extremely Helpful Rating Last Quarter
Agreement Monitor contacts	23.5%	20.8%
Newsletter	8.6%	2.1%
Toxicology testing	13.6%	13.5%
Website	4.9%	2.1%

For the quarter in descending order:

- 67.9% of respondents find the "Newsletters" "Helpful" / "Extremely Helpful."
- 63.0% of respondents find that "Agreement Monitor contacts" are "Helpful" / "Extremely Helpful."
- 56.8% of respondents find "Toxciology Testing" "Helpful" / "Extremely Helpful."
- 50.0% of OMB respondents find that "Individual Monitoring Consultants are "Helpful" / "Extremely Helpful."
- 49.4% of respondents find the "Website" "Helpful" / "Extremely Helpful."
- 47.4% of OMB respondents find that "Group Monitoring" is "Helpful" / "Extremely Helpful."

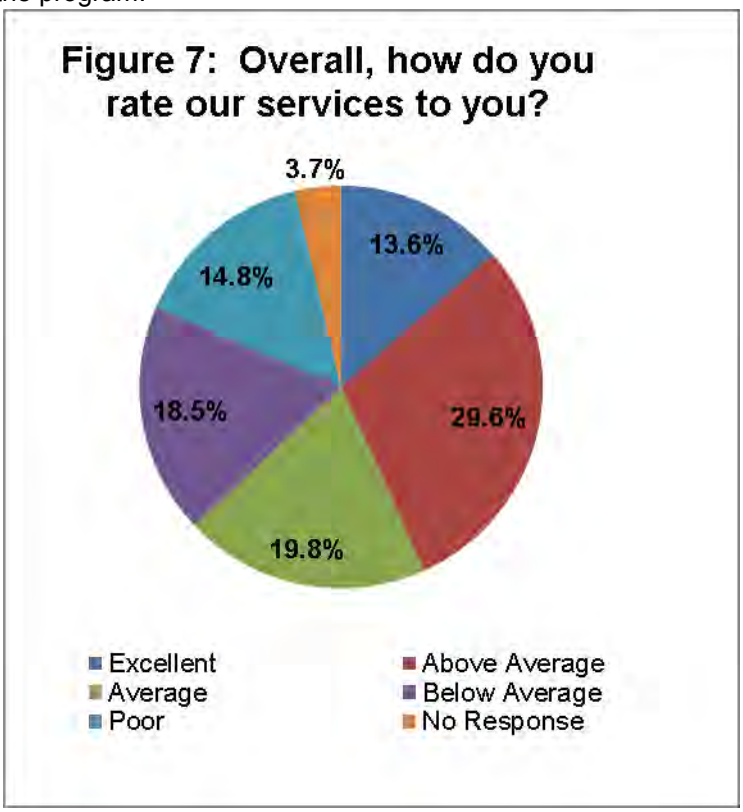
Percentages for the website and newsletters increased from last quarter's rates of 44.1% and 62.7% respectively. Percentages for Agreement Monitors and toxicology testing decreased from 69.8% and 68.1% respectively.



Overall Rating of Services

Respondents were asked to rate the overall services. This quarter 43.2% of all respondents rated the services as "Excellent" or "Above Average." This is comparable to last year's rate of 42% and last quarter's rate of 45.8%. This is a strong improvement from the 26.0% in year 1 of the program.

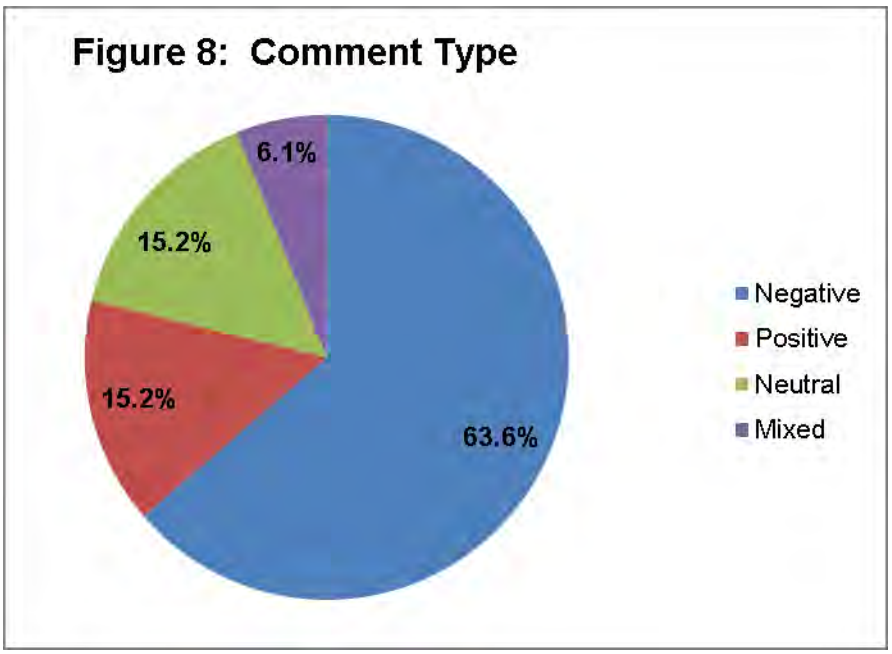
Table 7: Overall Rating	This Quarter (n=81)	
	#	%
Excellent	11	13.6%
Above Average	24	29.6%
Average	16	19.8%
Below Average	15	18.5%
Poor	12	14.8%
No Response	3	3.7%



Additional Comments

At the conclusion of the survey, respondents are asked for any additional comments. This quarter, 33 comments were re received, reviewed, and categorized. 40.7% of respondents provided a comment, which is similar to last quarter's comment rate of 40.6%.

Comments were first categorized with an overall type (See Figure 8): positive, negative, neutral or mixed (containing both positive and negative).



This quarter:

- 21 (63.6%) of the comments were negative (last year this percentage varied from 41% to 71%);
- 5 (15.2%) were positive (last year this percentage varied from 5% to 26%);
- 2 (6.1%) were mixed; and
- 5 (15.2%) were neutral.

Although we continue to see a higher percentage of negative comments, it is clear from a review of the results that the majority of comments are made by licensees who rated the program overall as "poor" or "below average" rather than "excellent" or "above average." Thus, it is not surprising that the comments are more negative than positive.

Comments were then categorized by area (see Data Table 8, next page). Each issue within a comment was categorized to maximize the ability to capture all feedback. Negative comments about the Program Structure continue to be the most frequent with 26.7% for the quarter.

Table 8: Categories of Comments Received		Quarter 1	
		#	%
Communication	Positive	0	0.0%
	Negative	2	4.4%
Financial Comp	Positive	0	0.0%
	Negative	2	4.4%
General	Positive	3	6.7%
	Negative	4	8.9%
	Neutral	1	2.2%
Mental Health Component	Positive	0	0.0%
	Negative	1	2.2%
Program Structure	Positive	0	0.0%
	Negative	**12**	**26.7%**
	Neutral	1	2.2%
Staff – Account Manager	Positive	4	8.9%
	Negative	1	2.2%
	Neutral	1	2.2%
Staff - General	Positive	0	0.0%
	Negative	1	2.2%
Staff Availability & Responsiveness	Positive	1	2.2%
	Negative	1	2.2%
Toxicology / Lab Locations	Positive	0	0.0%
	Negative	7	15.6%
	Neutral	2	4.4%
Website	Positive	0	0.0%
	Negative	1	2.2%

Actual Comments Received – October 2012

1. Rarely if ever does my monitor from HPSP R Health return my calls and if and when she does, it is several days later.
2. When my credit card didn't work the financial dept. did not call me to let me know. Instead there was a message stating that I was noncompliant. This message played when I called the daily toxicology number, and made me very worried/distressed. This was unnecessary stress that could have been avoided if they simply called me. Instead I spent all day wondering if I had been reported to the Board of Nursing.
3. Didn't know you had one (website) but would not access it anyway.
4. I think that having group with the implicit understanding that it is monitoring and not treatment is a colossal waste of time. How can anyone honestly discuss their issues knowing the sole purpose of the exercise is monitoring and has nothing to do with treatment? Also, I think you should make an extra effort to explain this difference to those who were in the past the previous HPP. I came in assuming it was treatment until I found out I cannot bill my health insurance as I could in the past program.
5. Right
6. In regards to dilute testing-there are other testing methods to assure no drug/alcohol use (blood test/hair test/mouth swab). It seems appropriate to offer these as an alternative to increased testing etc for dilute specimens. Expense is clearly not the only consideration and increasing testing frequency and doing more expensive "deeper delves" into dilute specimens is expensive as well. Increased testing only adds to the

possible stress of testing and trying to urinate in a short time frame etc-many drug testing places close early-many professionals work long hours.

7. I just want to thank [my Agreement Monitor] for everything she has done for me! Being in this program can be stressful at times. I have called in a panic and [my Agreement Monitor] is always on the other end of the phone to hear my concerns and do whatever she can to help me. [my Agreement Monitor] has been an advocate for me from day 1! She has been a great support through this process!
8. The program is overly burdensome, overly bureaucratic paper shuffling without a strong emphasis on rehabilitation. In other words more about boxes being checked than participant healing.
9. weekend testing sites are poor and not accommodating-stipulations often not compatible with case (no overtime, no preceptor etc). Would be very hesitant to recommend this program to a colleague in need.
10. I do not feel like this program is designed to suit each individual's needs based on their case. I feel like anybody that has had any incidence of drug or alcohol use is thrown into one group and is labeled as an 'addict' and receives the exact same treatment. I understand the regulations come from the associated boards but that is why I do not feel that this program is helpful.
11. Monthly employer evaluations for MDs are not useful or needed. Quarterly reports after the first year or two would suffice if any at all. Quarterly meeting with the HPSP consultants are useful and necessary for continued hospital and insurer acceptance. Please strongly consider discontinuing monthly employer evaluation forms after the first two years of monitoring.
12. worthless
13. [Name] is my agreement monitor and she is fantastic
14. I've been in the program 3 years and I feel this is way too long of a program.
15. Need to find a way to test overseas. Military institutions? Bringing a monitor with me? Hairtesting like previous HPP did? My work involves overseas work.
16. The last newsletter you had asked a very good question, about after three years why is a person still being treated like a new referral, with no consideration of their spotless record? Your answer really danced all around the question and did nothing to explain the reasons, other than the old, tired 'public safety", "Chronic disease" answers. Why not publish the TRUE reason? If you don't test a lot, you make less money. The money the state pays you is only the beginning, you make a lot more on the testing dollars from each person than you ever do from the state. This program is a joke and so is your medical director and your monitors. If people are going to be 'graduated' from the program at 4 years or so, you need to let people prove they can get through on their own without your lame-ass program.
17. This program is meant to protect the public and not help the physician. It makes people more depressed and drives other professionals who need recovery support away from getting help. The groups are particularly unhelpful because a large majority of what is talked about involves how agitating the HPSP program can be... This just perpetuates the unhappiness and anger. Of the only thing that's shown to work is toxicology, then why make the rest of the process so arduous?
18. RBH has been very professional and helpful to me with my case. Their professionalism is unparalleled in the business world today.
19. [Name] is my agreement monitor. she does a great job but I feel like weekly contact is excessive.
20. Basically RBH is a monitoring agency and states that they are not in the business of "recovery". So it is a little condescending to see "tips to stay sober" etc. in the newsletter. I do not recommend that people voluntarily enroll in this program.... we are treated like criminals and there is no flexibility in monitoring guidelines. I have read the statute that precipitated the demise of HPP and it looks like a lot of the guidelines are pulled out of the air... Has anyone ever asked why the enrollment numbers have declined so precipitously? The word is out that RBH is just out to make a buck with us.
21. I experience excessive testing.
22. [Name of collection site] is working on training its lab employees for e-file.
23. I appreciate and understand this program, but it is extremely costly to me with the frequency of testing. I believe there should be some drop in the testing for compliance. Continuous weekly testing is overboard, and costly. I do not understand 68 dollars for panel B and 103 for panel D!!! My testing while I was in outpatient treatment was $20dollars. Quite a difference for similar results. Ridiculous for weekly testing.
24. Not attuned to the needs of patients w mental illness which is not active.
25. I rated toxicology testing not very helpful due to the 3 hour drive I will experience if I am required to test on a Saturday. My local lab is closed on weekends.
26. [My Agreement Monitor] does an excellent job as well as many of the employees. But the general consensus is RBH is only in this for the money and uses our situation as leverage to make money. A terrible program overall and a comparison with the old HPP would border on the absurd. I definitely would not recommend it to any colleagues
27. Phone contact for weekly monitoring is extremely difficult and regularly not followed-up by agreement monitor. Entire program is extremely regimented and not individualized to address individual stressors/issues/challenges/situations. Very unsatisfied and I used to be able to see/receive information

regarding toxicology testing results and even though I am paying for the testing of my body fluid, I have not had access to any of my results nor information regarding my results...does anyone ever get information on compliance?

28. I would really like a closer Saturday testing site. Currently, it is 240 miles round trip.
29. I am grateful that I get to keep my license!!
30. Inconsistency seems to be a constant issue, ie different physicians being treated differently and/or lack of clarity on contract requirements. Does seem better on the later concern
31. The monitoring group is the least helpful in supporting my recovery. I enjoy visiting with peers, but my time (and money) could be better used attending a 12-step meeting, doing service work, etc. Since some of the group members don't believe they have an addiction and/or feel mistreated by HPSP or OMB, it is hard to have a positive, recovery-oriented discussion. I'm not aware of any evidence base supporting a non-therapeutic monitoring group. My suggestion: have one weekly monitoring contact, either monitoring group or phone call with agreement monitor but not both. This could be accomplished with a monthly group and weekly contact with the monitor the other weeks of the month.
32. I would like to have a personal contact at some point with my monitor
33. Program seems to be a work in progress...still needs work, although better than a year ago.

Summary Analysis

The licensee survey response rate was 25.8% for the quarter, down only slightly from last year's average response rate of 27.6%. However, this quarter's rate still represents a significant increase from year one's average response rate of 23%. The breakdown of respondents by board when compared to percentage of licensees enrolled in the program is most heavily skewed towards the Medical Board. The pool of respondents is not as representative of the entire population of licensees as we have seen in past surveys.

When thinking about their most recent call to RBH, 74.1% of respondents indicate that they "Agree" or "Strongly Agree" that their questions/concerns were responded to within 1 business day, with the majority of all respondents endorsing that they "Strongly Agree" with this item. This was the first time that "Strongly Agree" was the mode response for this item. 69.1% indicate that they "Agree" or "Strongly Agree" that information was communicated clearly and professionally; although this is a decrease from year 2's 76.6%, it is notable that, for the first time, the majority of all respondents indicated they "Strongly Agree" with this item. This appears to show increased polarization in feelings about the program, a trend that will be monitored in future surveys.

Agreement Monitors received strong ratings as they have in the past: 81.5% of respondents "Agree" or "Strongly Agree" that (his/her) Agreement Monitor is knowledgeable about (his/her) case. Similarly, 71.6% of respondents "Agree" or "Strongly Agree" that (his/her) needs and concerns are understood. In addition, the majority of all respondents on each item selected "Strongly Agree."

When rating how various components contribute towards the successful completion of the program, Agreement Monitor contacts, Newsletters, Toxicology testing and the Website were all most frequently rated as "Helpful." In addition, Medical Board licensees rated Individual Monitoring Consultants and Group Monitoring Consultants as "helpful" towards their successful completion of the program.

Overall, 43.2% of respondents rated the services as "Excellent" or "Above Average." This is comparable to last year's overall rating. As is typically seen in surveys, the comments were made by a greater percentage of the licensees who rated the program "Poor" or "Below Average." However, the survey responses overall are continuing to trend more positively.

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Prescription Drug Dispensing in Oregon

October 1, 2011 – March 31, 2012

Schedules II-IV Medications Dispensed in Oregon

Statewide

Oregon Health Authority
PUBLIC HEALTH DIVISION
Prescription Drug Monitoring Program

Prescription Controlled Substance Dispensing in Oregon: October 1, 2011 – March 31, 2012

Selected Schedule II – IV Medications

Statewide Data Report

Prescription Drug Monitoring Program

Center for Prevention and Health Promotion

Oregon Public Health Division

Oregon Health Authority

Technical Contact: Heidi Murphy, Heidi.R.Murphy@state.or.us

PDMP Program Contact: Todd Beran, Todd.Beran@state.or.us

October 2012

Acknowledgements

The following people serve on the data workgroup that guided the development of this report.

Dagan Wright, PhD, MPH
Center for Prevention & Health Promotion, Oregon Health Authority

Heidi Murphy, MPH
Center for Prevention & Health Promotion, Oregon Health Authority

Todd Beran, MA
Center for Prevention and Health Promotion, Oregon Health Authority

Brad Anderson, MD, Kaiser Permanente
Chief, Department of Addiction Medicine

Rick Deyo, MD, Professor, Department of Family Medicine, Oregon Health Sciences University

Sally Logan, RPh, Kaiser Permanente, Outpatient Pharmacy Quality Coordinator

Wayne Wakeland, PhD, Associate Professor, Systems Science Program, Portland State University

Gary Schnabel, RN, RPh, Executive Director, Oregon Board of Pharmacy

Ted Williams, Pharm.D, Pharmacy Director for Oregon Health Plan, and Oregon State University College of Pharmacy Faculty

The following staff contributed to the development of this report.

Lisa Millet, MSH
Injury & Violence Prevention Programs
Center for Prevention & Health Promotion, Oregon Health Authority

Bruce Gutelius, MD, MPH
Center for Prevention & Health Promotion, Oregon Health Authority

Katrina Hedberg, MD, MPH
State Epidemiologist, Chief Science Advisor, Office of State Public Health Officer, Oregon Public Health Division, Oregon Health Authority

Samantha Greene
Center for Prevention & Health Promotion, Oregon Health Authority

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Executive Summary

An alarming trend of prescription drug overdose, misuse and diversion has contributed to a significant increase in the number of prescription drug related deaths and hospitalizations in Oregon since 1999. In light of this trend, Senate Bill 355 was passed by the Oregon Legislature in 2009 to develop an electronic Prescription Drug Monitoring Program (PDMP). The system became operational in September 2011.

Oregon-licensed retail pharmacies are required to submit prescription information to the PDMP system for all Schedule II – IV controlled substances dispensed. Prescribers are permitted to access PDMP information on their patients. Pharmacists are permitted to access PDMP information on their customers. The intent of the PDMP is to help health care providers better treat their patients and prevent some of the problems associated with controlled substances.

Prescription drug data reports have been created for each of the 36 Oregon counties as well as a statewide report. The reports contain the top ten and selected prescription drugs broken down by age, prescription count, the average number of prescriptions per individual, rate of people per 1,000 receiving prescriptions, and rate of prescriptions dispensed per 1,000 residents. Also included are opioid and benzodiazepine combinations which indicate a greater risk for overdose. All county data are based on the address of the patient indicated on the prescription.

Purpose of Statewide and County-Level Reports

The reports provide data to state and county health officials that describe the amount of prescribed controlled substances that are dispensed by pharmacies in their counties and statewide. State and county officials need controlled substance dispensation information to inform policy decisions, develop prevention activities, and evaluate the effectiveness of prevention activities.

Data Limitations

The PDMP statute directs retail pharmacies dispensing schedule II-IV drugs to submit prescription data to the Oregon Health Authority within seven days of dispensing. Pharmacies began submitting data in June 2011. By October 2011, 76 percent of all pharmacies were submitting data. The compliance with data submission increased to 97 percent by the end of March 2012.

Data submitted by pharmacies can contain errors. Each data submission is checked for errors and if the data contains errors it is sent back to the pharmacy to correct errors. However, not all errors are found and corrected.

The sex of the patient, the method of payment used to purchase the prescription, diagnosis, and number of refills are not collected as they are not included in the data variables allowed in statute.

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The system is not able to convert prescriptions to morphine equivalent doses (MEDs), so dosage information is omitted from these reports to avoid possible confusion.

Data in table cells containing counts of less than ten are suppressed. This is done to protect the privacy of individuals when reporting county-specific data for each of Oregon's 36 counties.

Statewide Findings

Over 1.8 million prescriptions for opiates were dispensed by pharmacies to Oregonians between October 1, 2011 and March 31, 2012. Over 600,000 Oregonians received at least one prescription opiate between October 1, 2011 and March 31, 2012. These patients received an average of 3 opiate prescriptions during that period. Between October 1, 2011 and March 31, 2012, 159 people per 1,000 residents received an opiate prescription (Table 2).

Between October 1, 2011 and March 31, 2012, almost 109,000 Oregonians received prescriptions that included both an opiate and a benzodiazepine – a dangerous drug combination (Table 21).

The rate of people receiving prescriptions for opioids per 1,000 residents ranged from 155.1 per 1,000 residents in Lake County to 709.1 per 1,000 residents in Josephine County. Among the 36 counties, Lake County had consistently lower rates of prescriptions per 1,000 residents across all of the selected opioid types (all opioid, hydrocodone, oxycodone, morphine, methadone, and hydromorphone). The highest rates for all opioids and for hydrocodone were reported in Josephine County, while the highest rate for oxycodone was reported in Clackamas County, the highest rate for morphine was reported in Lincoln County, the highest rate for methadone was reported in Sherman County, and the highest rate for hydromorphone was reported in Lincoln County (Table 23).

Discussion

The PDMP data analysis is being guided by a data workgroup that includes experts in medicine, pain management, substance abuse, research, and epidemiology. This initial report is expected to generate questions and requests for further analysis. The literature on pain management estimates that from five to twenty percent of the population lives with chronic pain. There was no effort in this data analysis to distinguish between prescriptions for acute, post operative pain, cancer pain, and chronic pain in this report – there may be no way to do so. However, in future reports it may be possible to examine prescriptions for short-term relief of acute pain.

Prescription drug overdose, dependence, and addiction are serious public health problems. The PDMP provides healthcare providers with a tool to identify and address these problems. The PDMP mission is to use data to improve healthcare by providing healthcare providers and pharmacists with information about prescription controlled substances, reduce prescription overdose, and decrease doctor shopping and misuse of prescription controlled substances. A balanced approach to this work includes an understanding of the need to protect access to medicines for the management of pain while decreasing the misuse of prescription controlled substances. The PDMP data group welcomes input and questions.

Statewide Population

Table 1. Statewide, Oregon. Population, 2011*

Age (in years)	population
1 – 14	716384
15 – 24	507315
25 – 34	528317
35 – 44	505962
45 - 54	534643
55 - 64	512814
65 - 74	304927
75 - 84	169325
85+	77938
TOTAL	3857625

**2011 population estimates, Population Research Center, Portland State University.*

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Opiate Narcotic Analgesics

Table 2. Unique Recipient Count for Opioids by Age Group, Statewide, OR, 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescription, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	9944	12963	1.3	13.9	18.1
15 - 24	62185	110156	1.8	122.6	217.1
25 - 34	94114	241156	2.6	178.1	456.5
35 - 44	94866	295653	3.1	187.5	584.3
45 - 54	115983	432223	3.7	216.9	808.4
55 - 64	115612	425316	3.7	225.4	829.4
65 - 74	68418	220083	3.2	224.4	721.8
75 - 84	35663	108422	3.0	210.6	640.3
85+	16892	48662	2.9	216.7	624.4
TOTAL	**613677**	**1894634**	**3.1**	**159.1**	**491.1**

Opioids include: Hydrocodone, Oxycodone, Morphine, Methadone, Fentanyl, Carisoprodol, and Hydromorphone.

Notes on Table Information

Column 2 includes data for: Prescription recipients – these are number of **unique individuals who received prescriptions** in six months

Column 3 includes data for: Number of **prescriptions dispensed in the area** – either state or county in six months

Column 4 includes data for: Number of **prescriptions dispensed per prescription** (original and refills) per recipient in six months

Column 5 includes data for: A rate per 1,000 residents – the rate is the number of **people** who received a prescription per 1,000 residents.

Column 6 includes data for: A rate per 1,000 residents – the rate is the number of **prescriptions that individual people** received per 1,000 residents.

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Figure 1. Age adjusted rates of people receiving opioid prescriptions per 1,000, by all opioid type and county, OR, 10/1/2011 – 3/31/2012

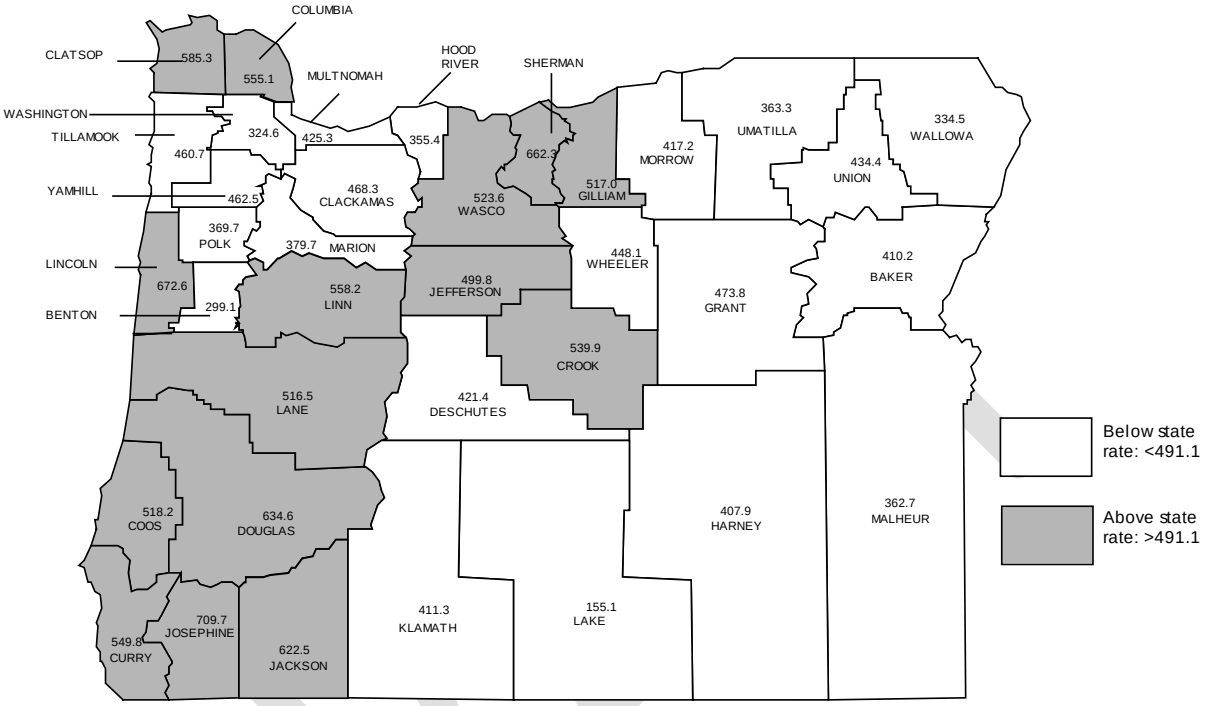

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Table 3. HYDROCODONE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	8442	10490	1.2	11.8	14.6
15 - 24	47183	72590	1.5	93.0	143.1
25 - 34	68100	138192	2.0	128.9	261.6
35 - 44	67805	159488	2.4	134.0	315.2
45 - 54	81033	220199	2.7	151.6	411.9
55 - 64	80197	216647	2.7	156.4	422.5
65 - 74	48505	122290	2.5	159.1	401.0
75 - 84	25679	63739	2.5	151.7	376.4
85+	11331	27231	2.4	145.4	349.4
TOTAL	**438275**	**1030866**	**2.4**	**113.6**	**267.2**

Table 4. OXYCODONE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	1656	2113	1.3	2.3	2.9
15 - 24	20491	34323	1.7	40.4	67.7
25 - 34	35791	83440	2.3	67.7	157.9
35 - 44	35349	96074	2.7	69.9	189.9
45 - 54	42693	135457	3.2	79.9	253.4
55 - 64	40757	127373	3.1	79.5	248.4
65 - 74	22603	61982	2.7	74.1	203.3
75 - 84	10109	26316	2.6	59.7	155.4
85+	4051	10611	2.6	52.0	136.1
TOTAL	**213500**	**577689**	**2.7**	**55.3**	**149.8**

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Table 5. MORPHINE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	49	94	1.9	0.1	0.1
15 - 24	305	779	2.6	0.6	1.5
25 - 34	1462	5928	4.1	2.8	11.2
35 - 44	3151	14575	4.6	6.2	28.8
45 - 54	6560	31859	4.9	12.3	59.6
55 - 64	7737	36011	4.7	15.1	70.2
65 - 74	4436	16868	3.8	14.5	55.3
75 - 84	2839	8316	2.9	16.8	49.1
85+	2621	4801	1.8	33.6	61.6
TOTAL	**29160**	**119231**	**4.1**	**7.6**	**30.9**

Table 6. METHADONE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	21	66	3.1	0.0	0.9
15 - 24	153	519	3.4	0.3	10.2
25 - 34	1298	5626	4.3	2.5	106.5
35 - 44	2333	10855	4.7	4.6	214.5
45 - 54	4086	19238	4.7	7.6	359.8
55 - 64	4083	19200	4.7	8.0	374.4
65 - 74	1437	6135	4.3	4.7	201.2
75 - 84	565	2052	3.6	3.3	121.2
85+	292	983	3.4	3.7	126.1
TOTAL	**14268**	**64674**	**4.5**	**3.7**	**167.7**

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Table 7. FENTANYL by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	76	144	1.9	0.1	0.2
15 - 24	84	256	3.0	0.2	0.5
25 - 34	472	1906	4.0	0.9	3.6
35 - 44	1071	4811	4.5	2.1	9.5
45 - 54	2090	9406	4.5	3.9	17.6
55 - 64	2585	10877	4.2	5.0	21.2
65 - 74	1806	6706	3.7	5.9	22.0
75 - 84	1567	5728	3.7	9.3	33.8
85+	1258	4431	3.5	16.1	56.9
TOTAL	**11009**	**44265**	**4.0**	**2.9**	**11.5**

Table 8. CARISOPRODOL by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	<10	6	<10	<10	0.01
15 - 24	250	443	1.77	0.49	0.87
25 - 34	988	2132	2.16	1.87	4.04
35 - 44	1663	4023	2.42	3.29	7.95
45 - 54	2890	7352	2.54	5.41	13.75
55 - 64	2620	6348	2.42	5.11	12.38
65 - 74	940	2055	2.19	3.08	6.74
75 - 84	278	593	2.13	1.64	3.50
85+	45	89	1.98	0.58	1.14
TOTAL	**9679**	**23041**	**2.38**	**2.51**	**5.97**

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Table 9. HYDROMORPHONE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	33	50	1.5	0.0	0.1
15 - 24	679	1242	1.8	1.3	2.4
25 - 34	1718	3908	2.3	3.3	7.4
35 - 44	2415	5806	2.4	4.8	11.5
45 - 54	3303	8664	2.6	6.2	16.2
55 - 64	3401	8792	2.6	6.6	17.1
65 - 74	1832	4020	2.2	6.0	13.2
75 - 84	755	1671	2.2	4.5	9.9
85+	230	511	2.2	3.0	6.6
TOTAL	**14366**	**34664**	**2.4**	**3.7**	**9.0**

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Benzodiazepines

Table 10. Unique Recipient Count for Benzodiazepines by Age Group, Statewide, OR, 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescription, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	3042	5576	1.8	4.2	7.8
15 - 24	14747	34050	2.3	29.1	67.1
25 - 34	36491	104792	2.9	69.1	198.4
35 - 44	49029	154875	3.2	96.9	306.1
45 - 54	66365	228140	3.4	124.1	426.7
55 - 64	71431	239665	3.4	139.3	467.4
65 - 74	41518	125315	3.0	136.2	411.0
75 - 84	22173	64585	2.9	130.9	381.4
85+	10758	28823	2.7	138.0	369.8
TOTAL	**315554**	**985821**	**3.1**	**81.8**	**255.6**

Benzodiazepines include: Alprazolam, Clonazepam, Diazepam, Lorazepam, Temazepam, and Zolpidem.

**Cell sizes less than 10 for prescription recipient count have been suppressed.*

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Table 11. ALPRAZOLAM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	457	734	1.6	0.6	1.0
15 - 24	3327	7120	2.1	6.6	14.0
25 - 34	9589	24384	2.5	18.2	46.2
35 - 44	12367	33280	2.7	24.4	65.8
45 - 54	15653	45428	2.9	29.3	85.0
55 - 64	15757	44856	2.8	30.7	87.5
65 - 74	8413	21804	2.6	27.6	71.5
75 - 84	4243	11219	2.6	25.1	66.3
85+	1859	4583	2.5	23.9	58.8
TOTAL	**71665**	**193408**	**2.7**	**18.6**	**50.1**

Table 12. CLONAZEPAM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	416	1232	3.0	0.6	1.7
15 - 24	2933	8084	2.8	5.8	15.9
25 - 34	7063	22286	3.2	13.4	42.2
35 - 44	8756	29975	3.4	17.3	59.2
45 - 54	11532	42089	3.6	21.6	78.7
55 - 64	11002	38341	3.5	21.5	74.8
65 - 74	5391	16991	3.2	17.7	55.7
75 - 84	2381	6970	2.9	14.1	41.2
85+	793	2318	2.9	10.2	29.7
TOTAL	**50267**	**168286**	**3.3**	**13.0**	**43.6**

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Table 13. DIAZEPAM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	1496	2265	1.5	2.1	3.2
15 - 24	2340	3573	1.5	4.6	7.0
25 - 34	5809	10850	1.9	11.0	20.5
35 - 44	7286	14966	2.1	14.4	29.6
45 - 54	9862	23560	2.4	18.4	44.1
55 - 64	9889	23351	2.4	19.3	45.5
65 - 74	5210	10838	2.1	17.1	35.5
75 - 84	2364	4731	2.0	14.0	27.9
85+	789	1590	2.0	10.1	20.4
TOTAL	**45045**	**95724**	**2.1**	**11.7**	**24.8**

Table 14. LORAZEPAM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	730	1162	1.6	1.0	1.6
15 - 24	5052	8765	1.7	10.0	17.3
25 - 34	10559	22071	2.1	20.0	41.8
35 - 44	13131	30683	2.3	26.0	60.6
45 - 54	17042	44837	2.6	31.9	83.9
55 - 64	18128	47925	2.6	35.4	93.5
65 - 74	11628	28596	2.5	38.1	93.8
75 - 84	7458	17791	2.4	44.0	105.1
85+	4973	10563	2.1	63.8	135.5
TOTAL	**88701**	**212393**	**2.4**	**23.0**	**55.1**

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Table 15. TEMAZEPAM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	15	29	1.9	0.0	0.0
15 - 24	233	473	2.0	0.5	0.9
25 - 34	652	1612	2.5	1.2	3.1
35 - 44	1252	3335	2.7	2.5	6.6
45 - 54	2289	6946	3.0	4.3	13.0
55 - 64	3288	10163	3.1	6.4	19.8
65 - 74	2369	6920	2.9	7.8	22.7
75 - 84	1713	4984	2.9	10.1	29.4
85+	937	2830	3.0	12.0	36.3
TOTAL	**12748**	**37292**	**2.9**	**3.3**	**9.7**

Table 16. ZOLPIDEM by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	85	154	1.8	0.1	0.2
15 - 24	2783	6032	2.2	5.5	11.9
25 - 34	8974	23575	2.6	17.0	44.6
35 - 44	14966	42619	2.8	29.6	84.2
45 - 54	21852	65244	3.0	40.9	122.0
55 - 64	25243	74999	3.0	49.2	146.2
65 - 74	14353	40147	2.8	47.1	131.7
75 - 84	6639	18885	2.8	39.2	111.5
85+	2456	6936	2.8	31.5	89.0
TOTAL	**97351**	**278591**	**2.9**	**25.2**	**72.2**

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Other Drugs

Table 17. AMPHET by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	7203	25845	3.6	10.1	36.1
15 - 24	8697	27620	3.2	17.1	54.4
25 - 34	7208	24901	3.5	13.6	47.1
35 - 44	5280	19249	3.6	10.4	38.0
45 - 54	4307	15748	3.7	8.1	29.5
55 - 64	3097	11347	3.7	6.0	22.1
65 - 74	664	2299	3.5	2.2	7.5
75 - 84	115	390	3.4	0.7	2.3
85+	26	86	3.3	0.3	1.1
TOTAL	**36597**	**127485**	**3.5**	**9.5**	**33.0**

Table 18. METHYLPHENIDATE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	14753	59596	4.0	20.6	83.2
15 - 24	6550	21251	3.2	12.9	41.9
25 - 34	2675	8504	3.2	5.1	16.1
35 - 44	2714	9246	3.4	5.4	18.3
45 - 54	2811	9781	3.5	5.3	18.3
55 - 64	2645	9456	3.6	5.2	18.4
65 - 74	869	2855	3.3	2.8	9.4
75 - 84	259	733	2.8	1.5	4.3
85+	109	307	2.8	1.4	3.9
TOTAL	**33385**	**121729**	**3.6**	**8.7**	**31.6**

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Table 19. ACETAMINOPHEN WITH CODEINE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	2212	2462	1.1	3.1	3.4
15 - 24	3984	4779	1.2	7.9	9.4
25 - 34	4265	5822	1.4	8.1	11.0
35 - 44	3842	6040	1.6	7.6	11.9
45 - 54	4493	8441	1.9	8.4	15.8
55 - 64	5380	11647	2.2	10.5	22.7
65 - 74	4095	8841	2.2	13.4	29.0
75 - 84	2809	6006	2.1	16.6	35.5
85+	1474	3048	2.1	18.9	39.1
TOTAL	**32554**	**57086**	**1.8**	**8.4**	**14.8**

Table 20. TESTOSTERONE by Age Group, Statewide, OR. 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving prescriptions, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	41	100	2.4	0.1	0.1
15 - 24	304	596	2.0	0.6	1.2
25 - 34	1062	2348	2.2	2.0	4.4
35 - 44	2929	6984	2.4	5.8	13.8
45 - 54	6457	15161	2.3	12.1	28.4
55 - 64	8357	19016	2.3	16.3	37.1
65 - 74	3548	7587	2.1	11.6	24.9
75 - 84	954	1918	2.0	5.6	11.3
85+	189	353	1.9	2.4	4.5
TOTAL	**23841**	**54063**	**2.3**	**6.2**	**14.0**

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Prescription Drug Combinations

Table 21. OPIOID and BENZODIAZEPINE Combination by Age Group, Statewide, OR, 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving combination, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	343	649	1.9	0.5	0.9
15 - 24	4642	13203	2.8	9.2	26.0
25 - 34	13336	54887	4.1	25.2	103.9
35 - 44	17700	79554	4.5	35.0	157.2
45 - 54	24664	123700	5.0	46.1	231.4
55 - 64	24216	114705	4.7	47.2	223.7
65 - 74	13148	53528	4.1	43.1	175.5
75 - 84	6862	24250	3.5	40.5	143.2
85+	3855	11270	2.9	49.5	144.6
TOTALS	**108766**	**475746**	**4.4**	**28.2**	**123.3**

‡Opioids include: Hydrocodone, Oxycodone, and Morphine. Benzodiazepines include: Alprazolam, Clonazepam, Diazepam, and Lorazepam. Excludes Zolpidem that represents a chemically different class of benzodiazepine, and in which the risk of combination with opioids is thought to be somewhat lower.

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Table 22. OPIOID and ZOLPIDEM/ZALEPLON Combination by Age Group, Statewide, OR, 10/01/11 to 03/31/12

Age (in years)	Prescription Recipient Count in 6 months	Number of prescriptions dispensed in 6 months	Number of prescriptions dispensed per prescription recipient in 6 months	Number of people receiving combination, per 1,000 residents	Number of prescriptions dispensed per 1,000 residents
1 - 14	12	16	1.3	0.0	0.0
15 - 24	923	2148	2.3	1.8	4.2
25 - 34	3633	10802	3.0	6.9	20.4
35 - 44	6079	19609	3.2	12.0	38.8
45 - 54	9252	31263	3.4	17.3	58.5
55 - 64	10378	34544	3.3	20.2	67.4
65 - 74	6020	18747	3.1	19.7	61.5
75 - 84	2694	8322	3.1	15.9	49.1
85+	926	2760	3.0	11.9	35.4
TOTALS	**39917**	**128211**	**3.2**	**10.3**	**33.2**

‡Opioids include: Hydrocodone, Oxycodone, and Morphine. Benzodiazepines include: Zolpidem and Zaleplon.

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Table 23. Rate of people receiving opioid prescriptions per 1,000, by prescription type, county and statewide, OR, 10/01/11 to 03/31/12

	All Opioid Rate	Hydro-codone Rate	Oxy-codone Rate	Morphine Rate	Methadone Rate	Hydro-morphone Rate	Opioid & Benzo Rate
Statewide	491.1	267.2	149.8	30.9	167.7	9.0	123.3
Baker	410.2	259.2	98.0	28.7	20.5	3.7	68.1
Benton	299.1	181.8	100.4	15.8	8.6	8.1	64.4
Clackamas	468.3	245.6	164.6	34.8	13.7	9.3	80.4
Clatsop	585.3	286.3	220.4	43.2	24.9	9.4	96.4
Columbia	555.1	288.9	196.8	39.2	21.5	8.6	88.5
Coos	518.2	356.5	98.7	31.6	21.3	10.0	103.6
Crook	539.9	339.4	148.7	24.9	18.8	7.6	95.5
Curry	549.8	387.6	93.7	41.4	20.9	6.1	121.1
Deschutes	421.4	268.7	133.9	21.2	11.3	10.3	95.2
Douglas	634.6	374.8	190.0	31.9	24.2	12.9	136.6
Gilliam	517.0	298.4	143.1	34.0	11.2	6.9	58.5
Grant	473.8	260.8	158.4	28.9	22.7	3.2	70.7
Harney	407.9	226.2	19.3	17.1	12.2	11.4	67.5
Hood River	355.4	233.1	93.7	17.4	21.3	7.1	57.3
Jackson	622.5	349.3	175.2	43.7	22.9	11.9	133.4
Jefferson	499.8	338.9	117.1	20.9	14.6	8.1	82.9
Josephine	709.7	420.8	192.3	41.3	39.9	9.3	219.5
Klamath	411.3	288.2	84.8	21.3	13.7	3.3	87.7
Lake	155.1	94.7	45.4	7.6	5.1	2.3	37.8
Lane	516.5	285.7	164.0	33.1	22.3	11.4	110.6
Lincoln	672.6	363.3	220.6	50.0	23.3	15.3	151.2
Linn	558.2	324.0	197.6	30.3	23.7	12.4	117.8
Malheur	362.7	290.6	55.0	14.7	15.6	1.5	70.9
Marion	379.7	229.0	126.5	22.5	15.5	8.3	74.3
Morrow	417.2	282.5	103.9	14.8	10.1	5.9	42.7
Multnomah	425.3	227.8	145.7	30.9	13.4	7.4	72.0
Polk	369.7	221.3	124.1	22.1	16.2	8.1	79.1
Sherman	662.3	420.4	115.0	22.1	92.9	11.9	93.5
Tillamook	460.7	251.6	136.6	38.9	24.0	9.5	117.5
Umatilla	363.3	239.9	96.4	13.0	8.0	6.0	77.9
Union	434.4	256.9	144.9	28.7	7.7	6.3	81.6
Wallowa	334.5	220.2	79.2	22.4	10.2	2.6	56.3
Wasco	523.6	304.4	142.9	30.1	38.4	7.8	81.7
Washington	324.6	188.0	119.8	24.4	9.3	7.5	61.3
Wheeler	448.1	271.8	102.4	39.7	11.1	5.6	76.0
Yamhill	462.5	249.8	150.4	37.3	16.4	8.5	77.6

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Glossary of Terms

Acetaminophen Acetaminophen is used to relieve mild to moderate pain and to reduce fever. It may also be used to relieve the pain of osteoarthritis (arthritis caused by the breakdown of the lining of the joints). It is often combined with opiates to increase their pain relieving properties. Acetaminophen has liver toxicity at higher doses. Acetaminophen is in a class of medications called analgesics (pain relievers) and antipyretics (fever reducers). It works by changing the way the body senses pain and by cooling the body.
Brand Names: Tylenol

Alprazolam Alprazolam is used to treat anxiety disorders and panic disorder (sudden, unexpected attacks of extreme fear and worry about these attacks). Alprazolam is in a class of medications called benzodiazepines. It works by decreasing abnormal excitement in the brain.
Brand names: Xanax

Amphet Amphet is identified as amphetamine and dextroamphetamine extended release and is commonly used to treat ADHD, fatigue and narcolepsy. Amphet is in a class of medications called central nervous system (CNS) stimulants.
Brand names: Adderall

Carisoprodol Carisoprodol, a muscle relaxant, is used with rest, physical therapy, and other measures to relax muscles and relieve pain and discomfort caused by strains, sprains, and other muscle injuries. It works by blocking pain sensations between the nerves and the brain and is a central nervous system (CNS) depressant.
Brand names: Soma

Clonazepam Clonazepam is used alone or in combination with other medications to control certain types of seizures. It is also used to relieve panic attacks. Clonazepam is in a class of medications called benzodiazepines. It works by decreasing abnormal electrical activity in the brain.
Brand names: Klonopin, Klonopin Wafer

Diazepam Diazepam is used to relieve anxiety, muscle spasms, and seizures and to control agitation caused by alcohol withdrawal. Diazepam is also used to treat irritable bowel syndrome and panic attacks. Diazepam is in a class of medications called benzodiazepines.
Brand names: Valium

Fentanyl Fentanyl is a powerful synthetic opiate analgesic similar to but more potent than morphine. It is typically used to treat patients with severe pain, or to manage pain after surgery. It is also sometimes used to treat people with chronic pain who are physically tolerant to opiates. Fentanyl is in a class of medications called opiate narcotic analgesics. It works by changing the way the brain and nervous system respond to pain.
Brand names: Abstral, Actiq, Duragesic, Fentora, Onsolis, Sublimaze

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Hydrocodone Hydrocodone is available only in combination with other ingredients, and different combination products are prescribed for different uses. Some hydrocodone products are used to relieve moderate to severe pain. Other hydrocodone products are used to relieve cough. Hydrocodone is in a class of medications called opiate narcotic analgesics and in a class of medications called antitussives. Hydrocodone relieves pain by changing the way the brain and nervous system respond to pain. Hydrocodone relieves cough by decreasing activity in the part of the brain that causes coughing.
Brand names: Vicodin, Lorcet, Lortab, Norco

Hydromorphone Hydromorphone is used to relieve moderate to severe pain. It also may be used to decrease coughing. Hydromorphone is in a class of medications called opiate narcotic analgesics and in a class of medications called antitussives.
Brand names: Dilaudid, Exalgo, Hydrostat, Palladone

Lorazepam Lorazepam is used to relieve anxiety. It is also used to treat irritable bowel syndrome, epilepsy, insomnia, and nausea and vomiting from cancer treatment and to control agitation caused by alcohol withdrawal. Lorazepam is in a class of medications called benzodiazepines. It works by slowing activity in the brain to allow for relaxation.
Brand names: Ativan

Methadone Methadone is used to relieve moderate to severe pain that has not been relieved by non-narcotic pain relievers. It also is used to prevent withdrawal symptoms in patients who were addicted to opiate drugs and are enrolled in treatment programs in order to stop taking or continue not taking the drugs. Methadone is in a class of medications called opiate narcotic analgesics. Methadone works to treat pain by changing the way the brain and nervous system respond to pain. It also works as a substitute for opiate drugs of abuse by producing similar effects and preventing withdrawal symptoms in people who have stopped using these drugs. Methadone has a very long half-life (stays in the body a long time).
Brand names: Dolophine, Methadose

Methylphenidate Methylphenidate is used as part of a treatment program to control symptoms of ADHD in adults and children. It is also used to treat narcolepsy. Methylphenidate is in a class of medications called central nervous system (CNS) stimulants. It works by changing the amounts of certain natural substances in the brain.
Brand names: Concerta, Metadate, Methylin, Ritalin

Morphine Morphine is used to relieve moderate to severe pain. Morphine long-acting tablets and capsules are only used by patients who are expected to need medication to relieve moderate to severe pain around-the-clock for longer than a few days. Morphine is in a class of medications called opiate narcotic analgesics. It works by changing the way the body senses pain.
Brand names: Avinza, Kadian, MS Contin, Oramorph, Roxanol

Oxycodone Oxycodone is used to relieve moderate to severe pain. Oxycodone is in a class of medications called opiate narcotic analgesics. It works by changing the way the brain and nervous system respond to pain.

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Brand names: Dazidox, Endocet, ETH-Oxydose, Endocodone, Oxecta, Oxy IR, Oxycontin, Oxyfast, Percocet, Percolone, Roxicodone

Temazepam Temazepam is used on a short-term basis to treat insomnia. Temazepam is in a class of medications called benzodiazepines. It works by slowing activity in the brain to allow sleep.
Brand names: Restoril

Testosterone Testosterone, a hormone that is usually produced by the body, contributes to the growth, development, and functioning of the male sexual organs and typical male characteristics. Symptoms of low testosterone include decreased sexual desire and ability, extreme tiredness, low energy, depression, and loss of certain male characteristics such as muscular build and deep voice. Testosterone patches work by providing a steady supply of testosterone through the skin to the body.
Brand names: Androderm, Androgel, Testim, Striant

Zolpidem Zolpidem is used to treat insomnia. Zolpidem belongs to a class of medications called sedative-hypnotics. It works by slowing activity in the brain to allow sleep.
Brand names: Ambien, Zolpimist

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UNFINISHED BUSINESS & RULES

Nothing to report under this tab

CORRESPONDENCE

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American Association of Dental Boards

October 23, 2012

Mr. Patrick Braatz
Executive Director
Oregon Board of Dentistry
1600 SW 4th Ave., Ste. 770
Portland, OR 1600 SW 4th Ave., Ste. 770

Dear Patrick:

I wanted to thank you once again for being the moderator at the Open Forum during this year's AADB Annual Meeting. You always do an excellent job and I appreciate the time you took preparing for the meeting.

Thank you again for joining us in San Francisco. It was great to see you!

Sincerely,

Molly Nadler
Executive Director

cc: Executive Council

211 E. Chicago Avenue • Suite 760 • Chicago, IL 60611 • (312)440-7464 • FAX: (312)440-3525

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American Academy of Sleep Medicine

American Academy of Dental Sleep Medicine

November 21, 2012

Patricia Parker, DMD
President
State of Oregon Board of Dentistry
1600 SW 4th Ave.
Suite 770
Portland, OR 97201

Dear Dr. Parker:

As the leading professional membership societies in the fields of sleep medicine and dental sleep medicine, the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) are committed to promoting the highest standards of care for patients with obstructive sleep apnea (OSA).

At least 12 to 18 million adults in the U.S. require treatment for OSA, a chronic medical disorder that is associated with deleterious medical conditions such as hypertension, stroke and congestive heart failure. The primary treatment options for adults with OSA are positive airway pressure (PAP) therapy and oral appliance therapy (OAT).

As the number of dentists who have begun to provide OAT has increased rapidly in recent years, both of our societies have received inquiries from members seeking clarification regarding the scope of practice of the physician and dentist in the diagnosis and long-term management of patients with OSA. Therefore, the AASM and AADSM collaboratively developed the attached Joint Policy Statement on the Diagnosis and Treatment of Obstructive Sleep Apnea, which provides the necessary guidance for our members and emphasizes the distinguishing facets of medical and dental licensing laws and practice acts.

The statement clearly assets that the diagnosis of OSA and the prescription of the appropriate treatment must be made by a qualified physician who is trained in sleep medicine. Once OAT has been prescribed by a board-certified sleep medicine physician, then the oral appliance device should be fit by a qualified dentist with training and experience in dental sleep medicine.

This joint policy statement will be made available to the 10,000 members of the AASM and the 3,000 members of the AADSM. Should you have any questions or comments about this statement, please contact Executive Director Jerome A. Barrett at 630-737-9700.

Phone: (630) 737-9705
Fax: (630) 737-9790
www.aadsm.org

2510 North Frontage Road, Darien, IL 60561-1511

Phone: (630) 737-9700
Fax: (630) 737-9790
www.aasmnet.org

It is our hope that your licensing board will find this statement to be useful should you need to respond to inquiries related to this issue.

Sincerely,

B. Gail Demko, DDS
AADSM President

Samuel A. Fleishman, MD
AASM President

Enclosure

cc: Jerome A. Barrett, Executive Director

American Academy of Sleep Medicine

American Academy of Dental Sleep Medicine

AMERICAN ACADEMY OF DENTAL SLEEP MEDICINE AND AMERICAN ACADEMY OF SLEEP MEDICINE JOINT POLICY STATEMENT ON THE DIAGNOSIS AND TREATMENT OF OBSTRUCTIVE SLEEP APNEA

The American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) are committed to the highest standards for sleep medicine care and ensuring patients receive quality care for obstructive sleep apnea (OSA).

OSA is a highly prevalent syndrome associated with deleterious medical conditions such as hypertension, stroke and congestive heart failure as well as health concerns such as increased motor vehicle accidents and impaired quality of life[i]; it is classified as a medical disorder.

The Diagnosis of Obstructive Sleep Apnea

It is the policy of the AASM and AADSM that patients presenting with symptoms of OSA require a face-to- face evaluation conducted by a qualified physician trained in sleep medicine. The AASM defines a qualified physician trained in sleep medicine as one who is licensed by a state to practice medicine and maintains certification from the American Board of Sleep Medicine or one of the sponsoring sleep medicine boards of the American Board of Medical Specialties.

Treatment Therapies for Obstructive Sleep Apnea

Therapies for OSA, including positive airway pressure (PAP) and oral appliance therapy (OAT), must be prescribed by a qualified physician as described above.

Qualified dentists with training and experience in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures should fit the oral appliance device[ii] as a therapy for OSA. Furthermore, dentists treating patients with OAT must practice within their scope of practice according to dental practice laws in their respective state. The AADSM defines a qualified dentist as one who maintains certification from the American Board of Dental Sleep Medicine[iii], or one who is the director of an AADSM-accredited dental facility and has completed 30 hours of continuing education (ADA CERP recognized or AGD PACE approved) within the past three years. With regard to continuing education, a minimum of 20 credits must be in dental sleep medicine. Additional credits must be sleep medicine related.

All qualified dentists must follow current AASM Practice Parameters and Clinical Guidelines and current AADSM Treatment Protocols.

Medical and Dental Licensing Laws and Practice Acts

The practice of medicine is governed by state licensing laws, which are commonly referred to as enabling laws. Enabling laws have a corresponding practice act, which governs the practice of medicine in the respective state; without this act any individual, regardless of qualifications, can practice medicine without restriction or penalty. The practice act also defines the scope and limits of practice for physicians. Because medicine is an ever-changing field, each practice act

Phone: (630) 737-9705
Fax: (630) 737-9790
www.aadsm.org

2510 North Frontage Road, Darien, IL 60561-1511

Phone: (630) 737-9700
Fax: (630) 737-9790
www.aasmnet.org

expires within a set period of time, which enables the state legislature to ensure that the respective laws are reflective of current medical practice.

Common provisions addressed by a practice act include but are not limited to:

- Provides for the delegation of patient care services to other professionals practicing within the scope of their license
- Outlines requirements for collaboration between physicians or dentists with other professionals
- Prohibits fee splitting
- Specifies limits for advertising
- Specifies requirements for continuing medical education and fitness for licensure
- Outlines terms of each license and conditions for renewal
- Specifies penalties for practicing medicine without a license or beyond the scope of license
- Outlines disciplinary action that can be taken including restriction, suspension or revocation of license

All medical practice acts restrict the diagnosis of a medical disease or disorder to a licensed physician. An individual who is not licensed in medicine yet diagnoses a medical disease or disorder is subject to civil and criminal law.

Medical practice laws and practice acts, however, do not include provisions for the performance of any dental operation.

Similar to medicine, licensing laws and practice acts for dentists include scope of practice and provisions for care.

Dental practice acts specify common provision that the performance of any dental operation upon the oral cavity, teeth or associated structure as well as the construction and fit of any appliance used in the oral cavity is under the purview of a licensed dentist.

Common provisions addressed by a dental practice act include but are not limited to:

- Provides for the delegation of patient care services to other professionals practicing within the scope of their license
- Specifies requirements for continuing medical education and fitness for licensure
- Outlines terms of each license and conditions for renewal
- Specifies penalties for practicing dentistry without a license or beyond the scope of license
- Outlines disciplinary action that can be taken including restriction, suspension or revocation of license
- Outlines the dentist's purview to take dental impressions for patients

Dental licensing laws and practice acts, however, do not include provisions for the diagnosis of medical diseases and disorders or the treatment of diseases by dentists without a prescription from a board certified physician. An individual who is not licensed in dentistry yet provides therapy related to the oral cavity is subject to civil and criminal law.

---

[i] Luyster FS; Strollo PJ; Zee PC; Walsh JK. Sleep: a health imperative. *SLEEP* 2012;35(6):727-734.

[ii] Kushida CA; Morgenthaler TI; Littner MR et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: An Update for 2005. *SLEEP* 2006;29(2): 240-243.

[iii] Certification by the American Board of Dental Sleep Medicine must be achieved on or prior to January 1, 2018.

OTHER ISSUES

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ADA American Dental Association®
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November 28, 2012

ADA updates dental radiograph recommendations

By Kelly Soderlund

The ADA, in collaboration with the Food and Drug Administration, has released updated recommendations for the prescription of dental radiographic examinations.

"Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Raditation Exposure," which was last updated in 2004, should serve in conjunction with dentists' professional judgment on when it's appropriate to use diagnostic imaging. Radiographs can help dentists evaluate and diagnose many oral diseases, but the ADA also recommends that dentists weigh the benefits of taking dental radiographs against the risk of exposing a patient to X-rays, the effects of which can accumulate from multiple sources over time.

The dentist is in the best position to make this call since he or she knows the patient's health history and their vulnerability to oral disease.

"We are encouraging dentists to look at the issue of selecting radiographic examinations for their patients on an individual basis, not as a one-size-fits-all," said Dr. Sharon Brooks, professor emeritus at the University of Michigan, who worked as a consultant with the ADA Council on Scientific Affairs to develop the new set of recommendations. "The guidelines are to help them make the decisions on the appropriate use."

It's important to have a concrete set of recommendations dentists can point to if patients have questions or concerns about the level of radiation they may be exposed to, Dr. Brooks said. The recommendations are intended to serve as a resource for the practitioner and are not intended to be standards of care, requirements or regulations.

The CSA and its consultants began working on updating the document about a year ago. It was then sent out for peer review to the American Academy of Oral and Maxillofacial Radiology; American Association of Endodontists; American Association of Orthodontists; American Academy of Periodontology; American Academy of Oral and Maxillofacial Pathology; American Academy of Pediatric Dentistry; American Association of Oral and Maxillofacial Surgeons; American College of Prosthodontists; American Association of Public Health Dentistry; and Academy of General Dentistry.

The nondental groups that were asked to review the recommendations included the FDA; National Council on Radiation Protection & Measurements; Conference of Radiation Control Program Directors; and American Association of Physicists in Medicine. Within the ADA, the recommendations were also sent for review to the councils on Dental Practice; Access, Prevention and Interprofessional Relations; Dental Education and Licensure; and Dental Benefit Programs.

Highlights from the updated document include:

• Removing a stronger recommendation for thyroid collar use for children, women of childbearing age and pregnant women. The strength of the recommendation is now the same for all patients.

• A new section that was not in the 2004 document, which expands upon the 2006 CSA report, "The Use of Dental Radiographs: Update and Recommendations."

• New topics that were not covered in the 2006 CSA report such as receptor selection, handheld X-ray units, technique charts and radiation risk communication.

• Changing the recommendation for shielding to be consistent with the National Council on Radiation Protection & Measurements.

To view the report in its entirety, visit www.ada.org/5160.aspx?currentTab=2.

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Radiography (X-ray)

Dentist Version

- Radiation Exposure
- Radiation Safety Requirements
- Guide to Patient Selection and Limiting Radiation Exposure
- Additional Resources

Radiation Exposure

Radiation exposure associated with dentistry represents a minor contribution to the total exposure from all sources (about 0.2 percent). The National Council on Radiation Protection and Measurements (NCRP)[1] has estimated that the mean effective radiation dose equivalent from all sources in the United States is 3.6 millisieverts (mSv) per year, with about 3 mSv of this dose from natural sources and about 0.6 mSv from manmade sources. The majority of manmade radiation exposure is medical-related. It is estimated that dental X-rays contribute approximately one percent of the total dose of exposure in health care settings.[2]

Occupational exposure in dental settings is far lower than that in hospitals and medical offices. According to the NCRP, the total limit for occupational exposure is 50 mSv in one year. In addition, the lifetime occupational effective dose is limited to 10 mSv times the number of an individual's age. The NCRP concludes that occupational exposure for dental personnel will not exceed these limits, excepting for problems associated with facility design, diagnostic equipment performance, or operating procedures. For pregnant dental personnel, the radiation exposure limit is 0.5 mSv per month.

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Radiation Safety Requirements

State laws and regulations set specific requirements for the use of ionizing radiation (which includes X-rays). Contact the state radiation protection program to determine specific requirements for:

- Inspection and testing for the facility, X-ray machine, radiation monitoring equipment and radiograph processing equipment
- Permits or licensing
- Supervision of personnel
- Use of dosimetry badges
- Training or certification
- Dental office design and radiation shielding

- Record keeping
- Equipment

Radiographic training requirements for dental office personnel frequently differ from and are less rigorous than those of medical personnel who take X-ray. Training requirements for dental office personnel typically are found in state dental practice acts or dental board regulations.

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Guide to Patient Selection and Limiting Radiation Exposure

The ADA, in collaboration with the FDA, developed recommendations for dental radiographic examinations to serve as an adjunct to the dentist's professional judgment of how to best use diagnostic imaging. Radiographs can help the dental practitioner evaluate and definitively diagnose many oral diseases and conditions. However, the dentist must weigh the benefits of taking dental radiographs against the risk of exposing a patient to X-rays, the effects of which accumulate from multiple sources over time. The dentist, knowing the patient's health history and vulnerability to oral disease, is in the best position to make this judgment. For this reason, the recommendations are intended to serve as a resource for the practitioner and are not intended to be standards of care, nor requirements or regulations.

Recommendations for Patient Selection and Limiting Radiation Exposure (PDF)

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Additional Resources

Managing Silver and Lead Waste in a Dental Office (PDF)

Directory of Dental Waste Recyclers (PDF)

The Health Physics Society (Occupational and Environmental Radiation Safety)

FDA - Dental Radiography: Doses and Film Speed

Radiation and Pregnancy: A Fact Sheet for the Public (Centers for Disease Control and Prevention)

ADA News: ADA Releases Statement on Dental X-rays Study

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[1] National Council on Radiation Protection and Measurements. Radiation Protection in Dentistry. 2003. NCRP Report No. 145.

[2] Aroua A Burnand B, Decka I, Vader JP, Valley JF. Nation-wide survey on radiation doses in diagnostic and interventional radiology in Switzerland in 1998. Health Phys 2002;83:46-55.

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FDA

DENTAL RADIOGRAPHIC EXAMINATIONS: RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE

REVISED: 2012

AMERICAN DENTAL ASSOCIATION
Council on Scientific Affairs

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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DENTAL RADIOGRAPHIC EXAMINATIONS: RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE

BACKGROUND

The dental profession is committed to delivering the highest quality of care to each of its individual patients and applying advancements in technology and science to continually improve the oral health status of the U.S. population. These guidelines were developed to serve as an adjunct to the dentist's professional judgment of how to best use diagnostic imaging for each patient. Radiographs can help the dental practitioner evaluate and definitively diagnose many oral diseases and conditions. However, the dentist must weigh the benefits of taking dental radiographs against the risk of exposing a patient to x-rays, the effects of which accumulate from multiple sources over time. The dentist, knowing the patient's health history and vulnerability to oral disease, is in the best position to make this judgment in the interest of each patient. For this reason, the guidelines are intended to serve as a resource for the practitioner and are not intended as standards of care, requirements or regulations.

The guidelines are not substitutes for clinical examinations and health histories. The dentist is advised to conduct a clinical examination, consider the patient's signs, symptoms and oral and medical histories, as well as consider the patient's vulnerability to environmental factors that may affect oral health. This diagnostic and evaluative information may determine the type of imaging to be used or the frequency of its use. Dentists should only order radiographs when they expect that the additional diagnostic information will affect patient care.

Based on this premise, the guidelines can be used by the dentist to optimize patient care, minimize radiation exposure and responsibly allocate health care resources.

This document deals only with standard dental imaging techniques of intraoral and common extraoral examinations, excluding cone-beam computed tomography (CBCT). At this time the indications for CBCT examinations are not well developed. The ADA Council on Scientific Affairs has developed a statement on use of CBCT.[1]

INTRODUCTION

The guidelines titled, "The Selection of Patients for X-Ray Examination" were first developed in 1987 by a panel of dental experts convened by the Center for Devices and Radiological Health of the U.S. Food and Drug Administration (FDA). The development of the guidelines at that time was spurred by concern about the U.S. population's total exposure to radiation from all sources. Thus, the guidelines were developed to promote the appropriate use of x-rays. In 2002, the American Dental Association, recognizing that dental technology and science continually advance, recommended to the FDA that

the guidelines be reviewed for possible updating. The FDA welcomed organized dentistry's interest in maintaining the guidelines, and so the American Dental Association, in collaboration with a number of dental specialty organizations and the FDA, published updated guidelines in 2004. This report updates the 2004 guidelines and includes recommendations for limiting exposure to radiation.

PATIENT SELECTION CRITERIA

Radiographs and other imaging modalities are used to diagnose and monitor oral diseases, as well as to monitor dentofacial development and the progress or prognosis of therapy. Radiographic examinations can be performed using digital imaging or conventional film. The available evidence suggests that either is a suitable diagnostic method.[2-4] Digital imaging may offer reduced radiation exposure and the advantage of image analysis that may enhance sensitivity and reduce error introduced by subjective analysis.[5]

A study of 490 patients found that basing selection criteria on clinical evaluations for asymptomatic patients, combined with selected periapical radiographs for symptomatic patients, can result in a 43 percent reduction in the number of radiographs taken without a clinically consequential increase in the rate of undiagnosed disease.[6,7] The development and progress of many oral conditions are associated with a patient's age, stage of dental development, and vulnerability to known risk factors. Therefore, the guidelines in Table 1 are presented within a matrix of common clinical and patient factors, which may determine the type(s) of radiographs that is commonly needed. The guidelines assume that diagnostically adequate radiographs can be obtained. If not, appropriate management techniques should be used after consideration of the relative risks and benefits for the patient.

Along the horizontal axis of the matrix, patient age categories are described, each with its usual dental developmental stage: child with primary dentition (prior to eruption of the first permanent tooth); child with transitional dentition (after eruption of the first permanent tooth); adolescent with permanent dentition (prior to eruption of third molars); adult who is dentate or partially edentulous; and adult who is edentulous.

Along the vertical axis, the type of encounter with the dental system is categorized (as "New Patient" or "Recall Patient") along with the clinical circumstances and oral diseases that may be present during such an encounter. The "New Patient" category refers to patients who are new to the dentist, and thus are being evaluated by the dentist for oral disease and for the status of dental development. Typically, such a patient receives a comprehensive evaluation or, in some cases, a limited evaluation for a specific problem. The "Recall Patient" categories describe patients who have had a recent comprehensive evaluation by the dentist and, typically, have returned as a patient of record for a periodic evaluation or for treatment. However, a "Recall Patient" may also return for a limited evaluation of a specific problem, a detailed and extensive evaluation for a specific problem(s), or a comprehensive evaluation.

Both categories are marked with a single asterisk that corresponds to a footnote that appears below the matrix; the footnote lists "Positive Historical Findings" and "Positive Clinical Signs/Symptoms" for which radiographs may be indicated. The lists are not intended to be all-inclusive, rather they offer the clinician further guidance on clarifying his or her specific judgment on a case.

The clinical circumstances and oral diseases that are presented with the types of encounters include: clinical caries or increased risk for caries; no clinical caries or no increased risk for caries; periodontal disease or a history of periodontal treatment; growth and development assessment; and other circumstances. A few examples of "Other Circumstances" proposed are: existing implants, other dental and craniofacial pathoses, endodontic/restorative needs and remineralization of dental caries. These examples are not intended to be an exhaustive list of circumstances for which radiographs or other imaging may be appropriate.

The categories, "Clinical Caries or Increased Risk for Caries" and "No Clinical Caries and No Increased Risk for Caries" are marked with a double asterisk that corresponds to a footnote that appears below the matrix; the footnote contains links to the ADA Caries Risk Assessment Forms (0 – 6 years of age and over 6 years of age). It should be noted that a patient's risk status can change over time and should be periodically reassessed.[8]

The panel also has made the following recommendations that are applicable to all categories:

1. Intraoral radiography is useful for the evaluation of dentoalveolar trauma. If the area of interest extends beyond the dentoalveolar complex, extraoral imaging may be indicated.
2. Care should be taken to examine all radiographs for any evidence of caries, bone loss from periodontal disease, developmental anomalies and occult disease.
3. Radiographic screening for the purpose of detecting disease before clinical examination should not be performed. A thorough clinical examination, consideration of the patient history, review of any prior radiographs, caries risk assessment and consideration of both the dental and the general health needs of the patient should precede radiographic examination.[9-15]

In the practice of dentistry, patients often seek care on a routine basis in part because oral disease may develop in the absence of clinical symptoms. Since attempts to identify specific criteria that will accurately predict a high probability of finding interproximal carious lesions have not been successful for individuals, it was necessary to recommend time-based schedules for making radiographs intended primarily for the detection of dental caries. Each schedule provides a range of recommended intervals that are derived from the results of research into the rates at which interproximal caries progresses through tooth enamel. The recommendations also are modified by criteria that place an individual at an increased risk for dental caries. Professional judgment

should be used to determine the optimum time for radiographic examination within the suggested interval.

RECOMMENDATIONS FOR PRESCRIBING DENTAL RADIOGRAPHS

These recommendations are subject to clinical judgment and may not apply to every patient. They are to be used by dentists only after reviewing the patient's health history and completing a clinical examination. Even though radiation exposure from dental radiographs is low, once a decision to obtain radiographs is made it is the dentist's responsibility to follow the ALARA Principle (As Low as Reasonably Achievable) to minimize the patient's exposure.

Table 1.

TYPE OF ENCOUNTER	PATIENT AGE AND DENTAL DEVELOPMENTAL STAGE				
	Child with Primary Dentition (prior to eruption of first permanent tooth)	**Child with Transitional Dentition** (after eruption of first permanent tooth)	**Adolescent with Permanent Dentition** (prior to eruption of third molars)	**Adult, Dentate or Partially Edentulous**	**Adult, Edentulous**
New Patient* being evaluated for oral diseases	Individualized radiographic exam consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be visualized or probed. Patients without evidence of disease and with open proximal contacts may not require a radiographic exam at this time.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images. A full mouth intraoral radiographic exam is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.		Individualized radiographic exam, based on clinical signs and symptoms.
Recall Patient* with clinical caries or at increased risk for caries**	Posterior bitewing exam at 6-12 month intervals if proximal surfaces cannot be examined visually or with a probe			Posterior bitewing exam at 6-18 month intervals	Not applicable
Recall Patient* with no clinical caries and not at increased risk for caries**	Posterior bitewing exam at 12-24 month intervals if proximal surfaces cannot be examined visually or with a probe		Posterior bitewing exam at 18-36 month intervals	Posterior bitewing exam at 24-36 month intervals	Not applicable

TYPE OF ENCOUNTER (continued)	**Child with Primary Dentition** (prior to eruption of first permanent tooth)	**Child with Transitional Dentition** (after eruption of first permanent tooth)	**Adolescent with Permanent Dentition** (prior to eruption of third molars)	**Adult, Dentate and Partially Edentulous**	**Adult, Edentulous**
Recall Patient* with periodontal disease	Clinical judgment as to the need for and type of radiographic images for the evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be demonstrated clinically.				Not applicable
Patient (New and Recall) for monitoring of dentofacial growth and development, and/or assessment of dental/skeletal relationships	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development or assessment of dental and skeletal relationships		Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships. Panoramic or periapical exam to assess developing third molars	Usually not indicated for monitoring of growth and development. Clinical judgment as to the need for and type of radiographic image for evaluation of dental and skeletal relationships.	
Patient with other circumstances including, but not limited to, proposed or existing implants, other dental and craniofacial pathoses, restorative/endodontic needs, treated periodontal disease and caries remineralization	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of these conditions				

***Clinical situations for which radiographs may be indicated include, but are not limited to:**

A. Positive Historical Findings

1. Previous periodontal or endodontic treatment
2. History of pain or trauma
3. Familial history of dental anomalies

4. Postoperative evaluation of healing
5. Remineralization monitoring
6. Presence of implants, previous implant-related pathosis or evaluation for implant placement

B. Positive Clinical Signs/Symptoms

1. Clinical evidence of periodontal disease
2. Large or deep restorations
3. Deep carious lesions
4. Malposed or clinically impacted teeth
5. Swelling
6. Evidence of dental/facial trauma
7. Mobility of teeth
8. Sinus tract ("fistula")
9. Clinically suspected sinus pathosis
10. Growth abnormalities
11. Oral involvement in known or suspected systemic disease
12. Positive neurologic findings in the head and neck
13. Evidence of foreign objects
14. Pain and/or dysfunction of the temporomandibular joint
15. Facial asymmetry
16. Abutment teeth for fixed or removable partial prosthesis
17. Unexplained bleeding
18. Unexplained sensitivity of teeth
19. Unusual eruption, spacing or migration of teeth
20. Unusual tooth morphology, calcification or color
21. Unexplained absence of teeth
22. Clinical tooth erosion
23. Peri-implantitis

∗∗Factors increasing risk for caries may be assessed using the ADA Caries Risk Assessment forms (0 – 6 years of age and over 6 years of age).

EXPLANATION OF RECOMMENDATIONS FOR PRESCRIBING DENTAL RADIOGRAPHS

The explanation below presents the rationale for each recommendation by type of encounter and patient age and dental developmental stages.

New Patient Being Evaluated for Oral Diseases

Child (Primary Dentition)
Proximal carious lesions may develop after the interproximal spaces between posterior primary teeth close. Open contacts in the primary dentition will allow a dentist to visually inspect the proximal posterior surfaces. Closure of proximal contacts requires radiographic assessment.[16-18] However, evidence suggests that many of these lesions will remain in the enamel for at least 12 months or longer depending on fluoride exposure, allowing sufficient time for implementation and evaluation of preventive interventions.[19-21] A periapical/anterior occlusal examination may be indicated because of the need to evaluate dental development, dentoalveolar trauma, or suspected pathoses. Periapical and bitewing radiographs may be required to evaluate pulp pathosis in primary molars.

Therefore, an individualized radiographic examination consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be examined visually or with a probe is recommended. Patients without evidence of disease and with open proximal contacts may not require radiographic examination at this time.

Child (Transitional Dentition)
Overall dental caries in the primary teeth of children from 2-11 years of age declined from the early 1970s until the mid 1990s.[22-24] From the mid 1990s until the 1999-2004 National Health and Nutrition Examination Survey, there was a small but significant increase in primary decay. This trend reversal was larger for younger children. Tooth decay affects more than one-fourth of U.S. children aged 2–5 years and half of those aged 12-15 years; however, its prevalence is not uniformly distributed. About half of all children and two-thirds of adolescents aged 12–19 years from lower-income families have had decay.[25]

Children and adolescents of some racial and ethnic groups and those from lower-income families have more untreated tooth decay. For example, 40 percent of Mexican American children aged 6–8 years have untreated decay, compared with 25 percent of non-Hispanic whites.[25] It is, therefore, important to consider a child's risk factors for caries before taking radiographs.

Although periodontal disease is uncommon in this age group,[26] when clinical evidence exists (except for nonspecific gingivitis), selected periapical and bitewing radiographs are indicated to determine the extent of aggressive periodontitis, other forms of uncontrolled periodontal disease and the extent of osseous destruction related to metabolic diseases.[27,28]

A periapical or panoramic examination is useful for evaluating dental development. A panoramic radiograph also is useful for the evaluation of craniofacial trauma.[15,29,30] Intraoral radiographs are more accurate than panoramic radiographs for the evaluation of dentoalveolar

trauma, root shape, root resorption[31,32] and pulp pathosis. However, panoramic examinations may have the advantage of reduced radiation dose, cost and imaging of a larger area.

Occlusal radiographs may be used separately or in combination with panoramic radiographs in the following situations: 1. unsatisfactory image in panoramic radiographs due to abnormal incisor relationship, 2. localizations of tooth position, and 3. when clinical grounds provide a reasonable expectation that pathosis exists.[32-34]

Therefore, an individualized radiographic examination consisting of posterior bitewings with panoramic examination or posterior bitewings and selected periapical images is recommended.

Adolescent (Permanent Dentition)

Caries in permanent teeth declined among adolescents, while the prevalence of dental sealants increased significantly.[35] However, increasing independence and socialization, changing dietary patterns, and decreasing attention to daily oral hygiene can characterize this age group. Each of these factors may result in an increased risk of dental caries. Another consideration, although uncommon, is the increased incidence of periodontal disease found in this age group compared to children.[36]

Panoramic radiography is effective in dental diagnosis and treatment planning.[30,37,38] Specifically, the status of dental development can be assessed using panoramic radiography.[39] Occlusal and/or periapical radiographs can be used to detect the position of an unerupted or supernumerary tooth.[40-42] Third molars also should be evaluated in this age group for their presence, position, and stage of development.

Therefore, an individualized radiographic examination consisting of posterior bitewings with panoramic examination or posterior bitewings and selected periapical images is recommended. A full mouth intraoral radiographic examination is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.

Adult (Dentate or Partially Edentulous)

The overall dental caries experience of the adult population has declined from the early 1970s until the most recent (1999-2004) National Health and Nutrition Examination Survey.[43] However, risk for dental caries exists on a continuum and changes over time as risk factors change.[44] Therefore, it is important to evaluate proximal surfaces in the new adult patient for carious lesions. In addition, it is important to examine patients for recurrent dental caries.

The incidence of root surface caries increases with age.[45] Although bitewing radiographs can assist in detecting root surface caries in proximal areas, the usual method of detecting root surface caries is by clinical examination.[46]

The incidence of periodontal disease increases with age.[47] Although new adult patients may not have symptoms of active periodontal disease, it is important to evaluate previous experience with periodontal disease and/or treatment. Therefore, a high percentage of adults may require selected intraoral radiographs to determine the current status of the disease.

Taking posterior bitewing radiographs of new adult patients was found to reduce the number of radiological findings and the diagnostic yield of panoramic radiography.[48,49] In addition, the following clinical indicators for panoramic radiography were identified as the best predictors for useful diagnostic yield: suspicion of teeth with periapical pathologic conditions, presence of partially erupted teeth, caries lesions, swelling, and suspected unerupted teeth.[50]

Therefore, an individualized radiographic examination, consisting of posterior bitewings with selected periapical images or panoramic examination when indicated is recommended. A full mouth intraoral radiographic examination is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.

Adult (Edentulous)

The clinical and radiographic examinations of edentulous patients generally occur during an assessment of the need for prostheses. The most common pathological conditions detected are impacted teeth and retained roots with and without associated disease.[51] Other less common conditions also may be detected: bony spicules along the alveolar ridge, residual cysts or infections, developmental abnormalities of the jaws, intraosseous tumors, and systemic conditions affecting bone metabolism.

The original recommendations for this group called for a full-mouth intraoral radiographic examination or a panoramic examination for the new, edentulous adult patient. Firstly, this recommendation was made because examinations of edentulous patients generally occur during an assessment of the need for prostheses. Secondly, the original recommendation considered edentulous patients to be at increased risk for oral disease.

Studies have found that from 30 to 50 percent of edentulous patients exhibited abnormalities in panoramic radiographs.[51-55] In addition, the radiographic examination revealed anatomic considerations that could influence prosthetic treatment, such as the location of the mandibular canal, the position of the mental foramen and maxillary sinus, and relative thickness of the soft tissue covering the edentulous ridge.[51,53,55] However, in studies that considered treatment outcomes, there was little evidence to support screening radiography for new edentulous patients. For example, one study reported that less than 4 percent of such findings resulted in treatment modification before denture fabrication, and another showed no difference in post-denture delivery complaints in patients who did not receive screening pretreatment radiographs.[54,56]

This panel concluded that prescription of radiographs is appropriate as part of the initial assessment of edentulous areas for possible prosthetic treatment. A full mouth series of periapical radiographs or a combination of panoramic, occlusal or other extraoral radiographs may be used to achieve diagnostic and therapeutic goals. Particularly with the option of dental implant therapy for edentulous patients,[57] radiographs can be an important aid in diagnosis, prognosis, and the determination of treatment complexity.

Therefore, an individualized radiographic examination, based on clinical signs, symptoms, and treatment plan is recommended.

Recall Patient with Clinical Caries or Increased Risk for Caries

Child (Primary and Transitional Dentition) and Adolescent (Permanent Dentition)
Clinically detectable dental caries may suggest the presence of proximal carious lesions that can only be detected with a radiographic examination. In addition, patients who are at increased risk for developing dental caries because of such factors as poor oral hygiene, high frequency of exposure to sucrose-containing foods, and deficient fluoride intake (see caries risk assessment forms, 0 – 6 years of age and over 6 years of age) are more likely to have proximal carious lesions.

The bitewing examination is the most efficient method for detecting proximal lesions.[16,18,58] The frequency of radiographic recall should be determined on the basis of caries risk assessment.[15,59,60] It should be noted that a patient's caries risk status may change over time and that an individual's radiographic recall interval may need to be changed accordingly.[61]

Therefore, a posterior bitewing examination is recommended at 6 to 12 month intervals if proximal surfaces cannot be examined visually or with a probe.

Adult (Dentate and Partially Edentulous)
Adults who exhibit clinical dental caries or who have other increased risk factors should be monitored carefully for any new or recurrent lesions that are detectable only by radiographic examination. The frequency of radiographic recall should be determined on the basis of caries risk assessment.[15,59,60] It should be noted that a patient's risk status can change over time and that an individual's radiographic recall interval may need to be changed accordingly.[61]

Therefore, a posterior bitewing examination is recommended at 6 to 18 month intervals.

Recall Patient (Edentulous Adult)

A study that assessed radiographs of edentulous recall patients showed that previously detected incidental findings did not progress and that no intervention was indicated.[62] The data suggest that patients who receive continuous dental care do not exhibit new findings that require treatment.

An examination for occult disease in this group cannot be justified on the basis of prevalence, morbidity, mortality, radiation dose, and cost.[53-55]

Therefore, no radiographic examination is recommended without evidence of disease.

Recall Patient with No Clinical Caries and No Increased Risk for Caries

Child (Primary and Transitional Dentition)
Despite the general decline in dental caries activity, recent data show that subgroups of children have a higher caries experience than the overall population.[63,64] The identification of

patients in these subgroups may be difficult on an individual basis. For children who present for recall examination without evidence of clinical caries and who are not considered at increased risk for the development of caries, it remains important to evaluate proximal surfaces by radiographic examination. In primary teeth the caries process can take approximately one year to progress through the outer half of the enamel and about another year through the inner half.[20,65-68] Considering this rate of progression of carious lesions through primary teeth, a time-based interval of radiographic examinations from one to two years for this group appears appropriate. The prevalence of carious lesions has been shown to increase during the stage of transitional dentition.[25,69] Children under routine professional care would be expected to be at a lower risk for caries. Nevertheless, newly erupted teeth are at risk for the development of dental caries.

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 12 to 24 months if proximal surfaces cannot be examined visually or with a probe.

Adolescent (Permanent Dentition)
Adolescents with permanent dentition, who are free of clinical dental caries and factors that would place them at increased risk for developing dental caries, should be monitored carefully for development of proximal carious lesions, which may only be detected by radiographic examination. The caries process, on average, takes more than three years to progress through the enamel.[20,65-68] However, evidence suggests that the enamel of permanent teeth undergoes posteruptive maturation and that young permanent teeth are susceptible to faster progression of carious lesions.[70-73]

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 18 to 36 months.

Adult (Dentate and Partially Edentulous)
Adult dentate patients, who receive regularly scheduled professional care and are free of signs and symptoms of oral disease, are at a low risk for dental caries. Nevertheless, consideration should be given to the fact that caries risk can vary over time as risk factors change. Advancing age and changes in diet, medical history and periodontal status may increase the risk for dental caries.

Therefore, a radiographic examination consisting of posterior bitewings is recommended at intervals of 24 to 36 months.

<u>Recall Patient with Periodontal Disease</u>

Child (Primary and Transitional Dentition), Adolescent (Permanent Dentition), and Adult (Dentate and Partially Edentulous)
The decision to obtain radiographs for patients who have clinical evidence or a history of periodontal disease/treatment should be determined on the basis of the anticipation that important diagnostic and prognostic information will result. Structures or conditions to be assessed should include the level of supporting alveolar bone, condition of the interproximal bony crest, length and shape of roots, bone loss in furcations, and calculus deposits. The

frequency and type of radiographic examinations for these patients should be determined on the basis of a clinical examination of the periodontium and documented signs and symptoms of periodontal disease. The procedure for prescribing radiographs for the follow-up/recall periodontal patient would be to use selected intraoral radiographs to verify clinical findings on a patient-by-patient basis.[28,74]

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be identified clinically.

Patient (New and Recall) for Monitoring of Dentofacial Growth and Development, and/or Assessment of Dental/Skeletal Relationships

Child (Primary and Transitional Dentition)
For children with primary dentition, before the eruption of the first permanent tooth, radiographic examination to assess growth and development in the absence of clinical signs or symptoms is unlikely to yield productive information. Any abnormality of growth and development suggested by clinical findings should be evaluated radiographically on an individual basis. After eruption of the first permanent tooth, the child may have a radiographic examination to assess growth and development. This examination need not be repeated unless dictated by clinical signs or symptoms. Cephalometric radiographs may be useful for assessing growth, and/or dental and skeletal relationships.

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships.

Adolescent (Permanent Dentition)
During adolescence there is often a need to assess the growth status and/or the dental and skeletal relationships of patients in order to diagnose and treat their malocclusion. Appropriate radiographic assessment of the malocclusion should be determined on an individual basis.

An additional concern relating to growth and development for patients in this age group is to determine the presence, position and development of third molars. This determination can best be made by the use of selected periapical images or a panoramic examination, once the patient is in late adolescence (16 to 19 years of age).

Therefore, it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships. Panoramic or periapical examination may be used to assess developing third molars.

Adult (Dentate, Partially Edentulous and Edentulous)
In the absence of any clinical signs or symptoms suggesting abnormalities of growth and development in adults, no radiographic examinations are indicated for this purpose.

Therefore, in the absence of clinical signs and symptoms, no radiographic examination is recommended.

Patients with Other Circumstances
(including, but not limited to, proposed or existing implants, other dental and craniofacial pathoses, restorative/endodontic needs, treated periodontal disease and caries remineralization)

All Patient Categories
The use of imaging, as a diagnostic and evaluative tool, has progressed beyond the longstanding need to diagnose caries and evaluate the status of periodontal disease. The expanded technology in imaging is now used to diagnose other orofacial clinical conditions and evaluate treatment options. A few examples of other clinical circumstances are the use of imaging for dental implant treatment planning, placement, or evaluation; the monitoring of dental caries and remineralization; the assessment of restorative and endodontic needs; and the diagnosis of soft and hard tissue pathoses.

Therefore it is recommended that clinical judgment be used in determining the need for, and type of radiographic images necessary for, evaluation and/or monitoring in these circumstances.

LIMITING RADIATION EXPOSURE

Dental radiographs account for approximately 2.5 percent of the effective dose received from medical radiographs and fluoroscopies.[75] Even though radiation exposure from dental radiographs is low, once a decision to obtain radiographs is made it is the dentist's responsibility to follow the ALARA Principle (As Low as Reasonably Achievable) to minimize the patient's exposure. Examples of good radiologic practice include

- use of the fastest image receptor compatible with the diagnostic task (F-speed film or digital);
- collimation of the beam to the size of the receptor whenever feasible;
- proper film exposure and processing techniques;
- use of protective aprons and thyroid collars, when appropriate; and
- limiting the number of images obtained to the minimum necessary to obtain essential diagnostic information.

RECEPTOR SELECTION
The American National Standards Institute and the International Organization for Standardization have established standards for film speed.[76,77] Film speeds available for dental radiography are D-speed, E-speed and F-speed, with D-speed being the slowest and F-speed the fastest. According to the U.S. Food and Drug Administration, switching from D to E speed can produce a 30 to 40 percent reduction in radiation exposure.[78] The use of F-speed film can reduce exposure 20 to 50 percent compared to use of E-speed film, without compromising diagnostic quality.[79-85]

Exposure of extraoral films such as panoramic radiographs requires intensifying screens to minimize radiation exposure to patients. The intensifying screen consists of layers of phosphor crystals that fluoresce when exposed to radiation. In addition to the radiation incident on the film, the film is exposed primarily to the light emitted from the intensifying screen. Previous generations of intensifying screens were composed of phosphors such as calcium tungstate. However, rare-earth intensifying screens are recommended because they reduce a patient's radiation exposure by 50 percent compared with calcium tungstate-intensifying screens.[86-89] Rare-earth film systems, combined with a high-speed film of 400 or greater, can be used for panoramic radiographs.[86] Older panoramic equipment can be retrofitted to reduce the radiation exposure to accommodate the use of rare-earth, high-speed systems.

Digital imaging provides an opportunity to further reduce the radiation dose by 40 to 60 percent.[90-93] In digital radiography, there are three types of receptors that take the place of conventional film: charge-coupled device (CCD), complementary-metal-oxide-semiconductor (CMOS), and photo-stimulable phosphor (PSP) plates. Systems that use CCD and CMOS-based, solid-state detectors are called "direct." When these sensors receive energy from the x-ray beam, the CCD or CMOS chip sends a signal to the computer and an image appears on the monitor within seconds. Systems that use PSP plates are called "indirect." When these plates are irradiated, a latent image is stored on them. The plate is then scanned and the scanner transmits the image to the computer.

RECEPTOR HOLDERS

Holders that align the receptor precisely with the collimated beam are recommended for periapical and bitewing radiographs. Heat-sterilizable or disposable intraoral radiograph receptor-holding devices are recommended for optimal infection control.[94] Dental professionals should not hold the receptor holder during exposure.[86] Under extraordinary circumstances in which members of the patient's family (or other caregiver) must provide restraint or hold a receptor holder in place during exposure, such a person should wear appropriate shielding.[86]

COLLIMATION

Collimation limits the amount of radiation, both primary and scattered, to which the patient is exposed. An added benefit of rectangular collimation is an improvement in contrast as a result of a reduction in fogging caused by secondary and scattered radiation.[89] The x-ray beam should not exceed the minimum coverage necessary, and each dimension of the beam should be collimated so that the beam does not exceed the receptor by more than 2 percent of the source-to-image receptor distance.[86] Since a rectangular collimator decreases the radiation dose by up to fivefold as compared with a circular one, [86,95,96] radiographic equipment should provide rectangular collimation for exposure of periapical and bitewing radiographs.[86] Use of a receptor-holding device minimizes the risk of cone-cutting (non-exposure of part of the image receptor due to malalignment of the x-ray beam). The position-indicating device should be open ended and have a metallic lining to restrict the primary beam and reduce the tissue volume exposed to radiation.[86] Use of long source-to-skin distances of 40 cm, rather than short distances of 20 cm, decreases exposure by 10 to 25 percent.[86,97] Distances between 20 cm and 40 cm are appropriate, but the longer distances are optimal.[86]

OPERATING POTENTIAL AND EXPOSURE TIME

The operating potential of dental x-ray units affects the radiation dose and backscatter radiation. Lower voltages produce higher-contrast images and higher entrance skin doses, and lower deep-tissue doses and levels of backscatter radiation. However, higher voltages produce lower contrast images that enable better separation of objects with differing densities. Thus, the diagnostic purposes of the radiograph should be used to determine the selection of kilovolt setting. A setting above 90 kV(p) will increase the patient dose and should not be used.[89] The optimal operating potential of dental x-ray units is between 60 and 70 kVp.[86,89]

Filmless technology is much more forgiving to overexposure often resulting in unnecessary radiation exposure. Facilities should strive to set the x-ray unit exposure timer to the lowest setting providing an image of diagnostic quality. If available, the operator should always confirm that the dose delivered falls within the manufacturer's exposure index. Imaging plates should be evaluated at least monthly and cleaned as necessary.

PATIENT SHIELDING AND POSITIONING

The amount of scattered radiation striking the patient's abdomen during a properly conducted radiographic examination is negligible.[98] The thyroid gland is more susceptible to radiation exposure during dental radiographic exams given its anatomic position, particularly in children.[93,99,100] Protective thyroid collars and collimation substantially reduce radiation exposure to the thyroid during dental radiographic procedures.[101,102] Because every precaution should be taken to minimize radiation exposure, protective thyroid collars should be used whenever possible. If all the recommendations for limiting radiation exposure are put into practice, the gonadal radiation dose will not be significantly affected by use of abdominal shielding.[86] Therefore, use of abdominal shielding may not be necessary.

Protective aprons and thyroid shields should be hung or laid flat and never folded, and manufacturer's instructions should be followed. All protective shields should be evaluated for damage (e.g. tears, folds, and cracks) monthly using visual and manual inspection.

Proper education and training in patient positioning is necessary to ensure that panoramic radiographs are of diagnostic quality.

OPERATOR PROTECTION

Although dental professionals receive less exposure to ionizing radiation than do other occupationally exposed health care workers,[75,86] operator protection measures are essential to minimize exposure. Operator protection measures include education, the implementation of a radiation protection program, occupational radiation exposure limits, recommendations for personal dosimeters and the use of barrier shielding.[103] The maximum permissible annual dose of ionizing radiation for health care workers is 50 millisieverts (mSv) and the maximum permissible lifetime dose is 10 mSv multiplied by a person's age in years.[86] Personal dosimeters should be used by workers who may receive an annual dose greater than 1 mSv to monitor their exposure levels. Pregnant dental personnel operating x-ray equipment should use personal dosimeters, regardless of anticipated exposure levels.[86]

Operators of radiographic equipment should use barrier protection when possible, and barriers should ideally contain a leaded glass window to enable the operator to view the patient during exposure.[86] When shielding is not possible, the operator should stand at least two meters from the tube head and out of the path of the primary beam.[103] The National Council on Radiation Protection & Measurements report "Radiation Protection in Dentistry" offers detailed information on shielding and office design.[86] State radiation control agencies can help assess whether barriers meet minimum standards.

HAND-HELD X-RAY UNITS

Hand-held, battery-powered x-ray systems are available for intra-oral radiographic imaging. The hand-held exposure device is activated by a trigger on the handle of the device. However, dosimetry studies indicate that these hand-held devices present no greater radiation risk than standard dental radiographic units to the patient or the operator. No additional radiation protection precautions are needed when the device is used according to the manufacturer's instructions. These include: 1. holding the device at mid-torso height, 2. orienting the shielding ring properly with respect to the operator, and 3. keeping the cone as close to the patient's face as practical. If the hand-held device is operated without the ring shield in place, it is recommended that the operator wear a lead apron.

All operators of hand-held units should be instructed on their proper storage. Due to the portable nature of these devices, they should be secured properly when not in use to prevent accidental damage, theft, or operation by an unauthorized user. Hand-held units should be stored in locked cabinets, locked storage rooms, or locked work areas when not under the direct supervision of an individual authorized to use them. Units with user-removable batteries should be stored with the batteries removed. Records listing the names of approved individuals who are granted access and use privileges should be prepared and kept current.

FILM EXPOSURE AND PROCESSING

All film should be processed following the film and processer manufacturer recommendations. Once this is achieved, the x-ray operator can adjust the tube current and time and establish a technique that will provide consistent dental radiographs of diagnostic quality. Poor processing technique, including sight-developing, most often results in underdeveloped films, forcing the x-ray operator to increase the dose to compensate, resulting in patient and personnel being exposed to unnecessary radiation.

A safelight does not provide completely safe exposure for an indefinite period of time. Extraoral film is much more sensitive to fogging. The length of time for which a film can be exposed to the safelight should be determined for the specific safelight/film combination in use.

QUALITY ASSURANCE

Quality assurance protocols for the x-ray unit, imaging receptor, film processing, dark room, and patient shielding should be developed and implemented for each dental health care setting.[86] All quality assurance procedures, including date, procedure, results, and corrective action, should be logged for documentation purposes. A qualified expert should survey all x-ray units on their placement and should resurvey the equipment every four years or after any

changes that may affect the radiation exposure of the operator and others.[86] Surveys typically are performed by state agencies, and individual state regulations should be consulted regarding specific survey intervals. The film processor should be evaluated at its initial installation and on a monthly basis afterward. The processing chemistry should be evaluated daily, and each type of film should be evaluated monthly or when a new box or batch of film is opened.[86] Abdominal shielding and thyroid collars should be inspected visually for creases or clumping that may indicate voids in their integrity on a monthly basis.[86] Damaged abdominal shielding and collars should be replaced. Table 2 lists specific methods of quality assurance procedures, covering not only inspection of the x-ray unit itself but also of the film processor, the image receptor devices, the darkroom and abdominal shielding and collars.[103,104]

It is imperative that the operator's manual for all imaging acquisition hardware is readily available to the user, and that the equipment is operated and maintained following the manufacturer's instructions, including any appropriate adjustments for optimizing dose and image quality.

TECHNIQUE CHARTS/PROTOCOLS

Size-based technique charts/protocols with suggested parameter settings are important for ensuring that radiation exposure is optimized for all patients. Technique charts should be used for all systems with adjustable settings, such as tube potential, tube current, and time or pulses. The purpose of using the charts is to control the amount of radiation to the patient and receptor. Technique charts are tables that indicate appropriate settings on the x-ray unit for a specific anatomical area and will ensure the least amount of radiation exposure to produce a consistently good-quality radiograph.

Technique charts for intraoral and extraoral radiography should list the type of exam, the patient size (small, medium, large) for adults and a pediatric setting. The speed of film used, or use of a digital receptor, should also be listed on the technique chart. The chart should be posted near the control panel where the technique is adjusted for each x-ray unit. A technique chart that is regularly updated should be developed for each x-ray unit. The charts will also need to be updated when a different film or sensor, new unit, or new screens are used.

RADIATION RISK COMMUNICATION

Dentists should be prepared to discuss with their patients the benefits and risks of the x-ray exam.[105] To help answer patient and parent questions about dental radiology radiation safety, the American Academy of Oral and Maxillofacial Radiology and the Alliance for Radiation Safety in Pediatric Imaging partnered to create a brochure targeted at parents and patients.[106]

Table 2.

Quality Assurance Procedures for Assessment of Radiographic Equipment		
The following procedures for periodic assessment of the performance of radiographic equipment, film processing, equipment, image receptor devices, dark room integrity, and abdominal and thyroid shielding are adapted from the National Council for Radiation Protection and Measurements report, "Radiation Protection in Dentistry."[86] Please refer to state guidelines for specific regulations.		
Equipment	**Frequency**	**Method**
X-ray Machine	On installation At regular intervals as recommended by state regulations Whenever there are any changes in installation workload or operating conditions	Inspection by qualified expert (as specified by government regulations and manufacturers recommendations).
Film Processor	On installation Daily	**Method 1: Sensitometry and Densitometry** A sensitometer is used to expose a film, followed by standard processing of the film. The processed film will have a defined pattern of optical densities. The densities are measured with a densitometer. The densitometer measurements are compared to the densities of films exposed and processed under ideal conditions. A change in densitometer values indicates a problem with either the development time, temperature or the developer solutions. *Advantages* Accuracy Speed *Disadvantage* Expense of additional equipment **Method 2: Reference Film** A film exposed and processed under ideal conditions is attached to the corner of a view box as a reference film. Subsequent films are compared with the reference film. *Advantage* Cost effectiveness *Disadvantage* Less sensitive
Image Receptor Devices Intensifying Screen and	Monthly With each new batch of film Every six months	**Method 1: Sensitometry and Densitometry** (as described above) **Method 2: Reference Image** (as described above) Visual inspection of cassette integrity Examination of intensifying screen for

Extraoral Cassettes		scratches Development of an unexposed film that has been in the cassette exposed to normal lighting for one hour or more
Darkroom Integrity	On installation Monthly After a change in the lighting filter or lamp	While in a darkroom with the safelight on, place metal object (such as a coin) on unwrapped film for a period that is equivalent to the time required for a typical darkroom procedure Develop film Detection of the object indicates a problem with the safelight or light leaks in the darkroom
Abdominal and Thyroid Shielding	Monthly (visual and manual inspection)	All protective shields should be evaluated for damage (e.g., tears, folds, and cracks) monthly using visual and manual inspection. If a defect in the attenuating material is suspected, radiographic or fluoroscopic inspection may be performed as an alternative to immediately removing the item from service. Consideration should be given to minimizing the radiation exposure of inspectors by minimizing unnecessary fluoroscopy.

TRAINING AND EDUCATION

Where permitted by law, auxiliary dental personnel can perform intraoral and extraoral imaging.[103] Personnel certified to take dental radiographs should receive appropriate education. Practitioners should remain informed about safety updates and the availability of new equipment, supplies and techniques that could further improve the diagnostic quality of radiographs and decrease radiation exposure. Free training materials are available for limiting radiation exposure in dental imaging through the International Atomic Energy Agency.[107]

CONCLUSION

Dentists should conduct a clinical examination, consider the patient's oral and medical histories, as well as consider the patient's vulnerability to environmental factors that may affect oral health before conducting a radiographic examination. This information should guide the dentist in the determination of the type of imaging to be used, the frequency of its use, and the number of images to obtain. Radiographs should be taken only when there is an expectation that the diagnostic yield will affect patient care.

Dentists should develop and implement a radiation protection program in their offices. In addition, practitioners should remain informed on safety updates and the availability of new equipment, supplies, and techniques that could further improve the diagnostic ability of radiographs and decrease exposure.

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From:	Patrick Braatz
To:	Lisa Warwick
Subject:	Fwd: Notice of Proposed Rulemaking - 333-100 - 333-123 - Radiation Protection Services
Date:	Friday, November 16, 2012 6:12:49 PM
Attachments:	333-100 - 333-123 Notice of Hearing_AMENDED.pdf ATT00001.htm 333-100 - 333-123 Need and Fiscal.pdf ATT00002.htm 333-100 - 333-123 PROPOSED text_FINAL.pdf ATT00003.htm

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From: SANDE Brittany A [mailto:brittany.a.sande@state.or.us]
Sent: Friday, November 16, 2012 11:30 AM
To: brittany.a.sande@state.or.us
Subject: Notice of Proposed Rulemaking - 333-100 - 333-123 - Radiation Protection Services

Date: November 16, 2012

TO: Interested Parties

FROM: David Howe, Program Director
Radiation Protection Services
Oregon Health Authority, Public Health Division

RE: Notice of Proposed Rulemaking for changes to OAR chapter 333, divisions 100 through 123 – "Edits, amendments and adoption of rules related to Radiation Protection Service's programs"

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to permanently adopt, amend and repeal Oregon Administrative Rules (OAR) in chapter 333, divisions 100, 102, 106, 116, 118, 119, 120 and 123 related to programs within the Radiation Protection Services.

The Radiation Materials Licensing program is proposing to amend rules to comply with the Nuclear Regulatory Commission's 10 CFR Parts 1-50 to meet federal law pertaining to the medical use of radioactive material, clarifying the authorized material user's training requirements, and to amend the rule pertaining to the "180 day" term by revising to state "180 consecutive days" in relationship to reciprocity activities performed within the state.

The X-ray program is proposing to amend rules to recognize the Oregon Board of Medical Imaging's ORS 688.405 relating to radiologic technology training and to update the website addresses. The program proposes to adopt new rules in division 123 relating to the use of electronic brachytherapy machines. These units currently have no regulations to provide guidance to the user and the Authority's inspection staff. Also being revised is a rule to better define the definition of "Impracticable to transfer the patient to a stationary X-ray installation".

The Tanning program is proposing to amend rules to clarify construction and

operations of tanning facilities by adding additional rules ensuring that clean sanitary towels and a receptacle be provided for soiled towels, and not allowing pets in the tanning facilities. Also being proposed is the adoption of a new rule that allows the tanning registrant to follow the manufactures' guidelines for use of sanitation solutions and discontinue the regulation of requiring the Authority to maintain a list of approved sanitizers.

You are being invited to review the proposed rules and to comment on them. If you wish to present oral testimony, a public hearing will be held in Portland, Oregon at 800 NE Oregon St, Room 1B, on December 20, 2012 at 10:00 a.m. (see hearing notice). You may also file written comments before 5:00 p.m. on December 24, 2012 to the Public Health Division Rules Coordinator at the following address:

OHA, Public Health Division
Brittany Sande, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, OR 97232

E-mail comments to:
brittany.a.sande@state.or.us<mailto:brittany.a.sande@state.or.us> or by fax to (971) 673-1299

For more details, please see the attached Notice of Proposed Rulemaking Hearing, Statement of Need and Fiscal Impact, and the full text of the proposed rules.

If you have any questions or would prefer a hardcopy be sent, please contact Todd Carpenter at 971-673-0500.

AMENDED

Secretary of State

NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority, Public Health Division	333
Agency and Division	Administrative Rules Chapter Number

Brittany Sande	800 NE Oregon St., Suite 930, Portland, Oregon, 97232	971-673-1291
Rules Coordinator	Address	Telephone

RULE CAPTION

Edits, amendments and adoption of rules related to Radiation Protection Service's programs

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

December 20, 2012	10:00 AM	Portland State Office Building, 800 NE Oregon St. Room 1B Portland, Oregon, 97232	Jana Fussell
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT: 333-119-0041, 333-123-0055, 333-123-0060, 333-123-0065, 333-123-0070, 333-123-0075, 333-123-0080, 333-123-0085, 333-123-0090, 333-123-0095, 333-123-0100, 333-123-0105, 333-123-0110, 333-123-0115

BS 11/15/12

AMEND: 333-100-0005, 333-102-0115, 333-102-0203, 333-102-0250~~333-120-0250~~, 333-102-0285, 333-102-0340, 333-106-0045, 333-106-0101, 333-106-0305, 333-106-0315, 333-106-0325, 333-106-0370, 333-106-0720, 333-116-0040, 333-116-0050, 333-116-0090, 333-116-0640, 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0715, 333-116-0720, 333-116-0740, 333-116-0880, 333-116-0905, 333-118-0150, 333-119-0040, 333-119-0080, 333-120-0630, 333-120-0730, 333-123-0005

REPEAL: 333-116-0405

RENUMBER:

AMEND & RENUMBER:

Stat. Auth. : ORS 431.925 - 431.955 & 453.605 - 453.807

Other Auth.: Nuclear Regulatory Commission's 10 CFR Parts 1 through 50

Stats. Implemented: ORS 431.930 & 453.605 - 453.807

RULE SUMMARY

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to permanently adopt, amend and repeal Oregon Administrative Rules (OAR) in chapter 333, divisions 100, 102, 106, 116, 118, 119, 120 and 123 related to programs within the Radiation Protection Services.

The Radiation Materials Licensing program is proposing to amend rules to comply with the Nuclear Regulatory Commission's 10 CFR Parts 1-50 to meet federal law pertaining to the medical use of radioactive material, clarifying the authorized material user's training requirements, and to amend the rule pertaining to

the "180 day" term by revising to state"180 consecutive days" in relationship to reciprocity activities performed within the state.

The X-ray program is proposing to amend rules to recognize the Oregon Board of Medical Imaging's ORS 688.405 relating to radiologic technology training and to update the website addresses. The program proposes to adopt new rules in division 123 relating to the use of electronic brachytherapy machines. These units currently have no regulations to provide guidance to the user and the Authority's inspection staff. Also being revised is a rule to better define the definition of "Impracticable to transfer the patient to a stationary X-ray installation".

The Tanning program is proposing to amend rules to clarify construction and operations of tanning facilities by adding additional rules ensuring that clean sanitary towels and a receptacle be provided for soiled towels, and not allowing pets in the tanning facilities. Also being proposed is the adoption of a new rule that allows the tanning registrant to follow the manufactures' guidelines for use of sanitation solutions and discontinue the regulation of requiring the Authority to maintain a list of approved sanitizers.

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.

December 24, 2012 by 5:00 p.m.

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

Brittany Sande — Brittany Sande, Administrative Rules Coordinator — 11/14/12

Signature — Printed name — Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Public Health Division — 333

Agency and Division — Administrative Rules Chapter Number

Edits, amendments and adoption of rules related to Radiation Protection Services

Rule Caption:

In the Matter of: Amending, adopting and repealing Oregon Administrative Rules in chapter 333, divisions 100, 102, 106, 116, 118, 119, 120 and 123 pertaining to Radiation Protection Services (RPS).

Statutory Authority: ORS 431.925 – 431.955 & 453.605 – 453.807

Other Authority: Nuclear Regulatory Commission's 10 CFR Parts 1 - 50

Stats. Implemented: ORS 431.930 & 453.605 – 453.807

Need for the Rule(s):

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to amend and adopt Oregon Administrative Rules related to programs within the Radiation Protection Services.

The Radiation Materials Licensing program is proposing to amend rules to comply with the Nuclear Regulatory Commission's 10 CFR Parts 1-50 to meet federal law pertaining to the medical use of radioactive material, and clarifying the authorized material user's training requirements. Also being proposed is to amend the rule pertaining to the "180 day" term by revising the term to "180 consecutive days" in relationship to reciprocity activities performed within the state.

The X-ray program is proposing to amend rules to recognize the Oregon Board of Medical Imaging's ORS 688.405 relating to radiologic technology training and to update the website addresses. The program proposes to adopt new rules in division 123 relating to the use of electronic brachytherapy machines. These units currently have no regulations providing guidance to the user and the Authority's inspection staff. Also being revised is a rule to better define the definition of "Impracticable to transfer the patient to a stationary X-ray installation".

The Tanning program is proposing to amend rules to clarify construction and operations of tanning facilities by adding additional rules ensuring that clean sanitary towels and a receptacle be provided for soiled towels, and not allowing pets in the tanning facilities. A proposal for the adoption of a new rule that allows the tanning registrant to follow the manufacturer's guidelines for use of sanitation solutions and discontinue the regulation of requiring the Authority to maintain a list of approved sanitizers.

Documents Relied Upon, and where they are available:

- Nuclear Regulatory Commission's Regulation Amendments (RATS) 2009-1: http://nrc-stp.ornl.gov/rss_regamendents.html
- 10 CFR Parts 1-50: http://www.nrc.gov/reading-rm/doc-collections/cfr/
- Conference of Radiation Control Program Directors suggested State Regulations, Part X, Therapeutic Radiation Machines: http://www.crcpd.org/ssrcr.aspx

- Current Oregon Administrative Rules:
  http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_tofc.html
- Oregon Revised Statues chapter 680:
  http://www.leg.state.or.us/ors/680.html

Fiscal and Economic Impact:
There is no anticipated fiscal impact to registrants or licensees within the Radiation Protection Services programs. The proposed rule adoptions and amendments are generated to compliment the registrant and licensee's business practices.

There is no anticipated fiscal impact to the Oregon Health Authority, other state agencies, or members of the public as a result of the proposed rules.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):
There is no cost of compliance impact on state agencies, units of local government or the public as a result of the proposed rule amendments.

2. Cost of compliance effect on small business (ORS 183.336):
a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:
The proposed rule amendments and adoption of a new rule for the tanning industry will affect approximately 523 small business owners which will require the registrant to establish new protocols addressing sanitation practices.

The Oregon Health Authority does not anticipate any cost increase to small businesses.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:
Tanning registrants will be required to develop and maintain sanitation procedure guidelines for the employee to follow regarding sanitizing practices for tanning beds used by the public.

c. Equipment, supplies, labor and increased administration required for compliance:
Radiation Protection Services has the programs in place for regulatory and registration oversight. No cost related to labor, capital expenditures or supplies are foreseen with these revisions.

How were small businesses involved in the development of this rule? Small businesses directed the Radiation Protection Services Inspection program to become more engaged with the business owner and respond to the suggestions of providing clarity of the sanitation rule and allowing the registrant to become more independent in selecting sanitizing agents. Small businesses will also be included when the notice of proposed rulemaking is sent to interested parties prior to the public hearing and comment period.

Administrative Rule Advisory Committee consulted?: Yes. Committee members represent both the registrant and the licensee and include TDY Industries, Inc., Legacy Health Care Systems, Oregon Health and Science University, Oregon State University, Providence Health Care, University of Oregon, and Oregon Health and Science University School of Dentistry.

If not, why?:

Brittany Sande	Brittany Sande, Administrative Rules Coordinator	11/14/12
Signature	Printed name	Date

Underlined text is being added. ~~Strikethrough text~~ is being deleted.

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 100

CONTROL OF RADIATION IN OREGON

General Requirements

333-100-0005

Definitions

The following definitions apply to OAR chapter 333 divisions 100, 102, 103, 106, 111, 116, 118, 119, 120, 121, 122, 123, and 124. Additional definitions used only in a certain division ~~will~~can be found in that division.

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

(3) "Accelerator-produced material" means any material made radioactive by a particle accelerator.

(4) "Act" means Oregon Revised Statutes 453.605 through 453.807.

(5) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq), defined as one disintegration per second, and the curie (Ci), defined as 3.7×10^{10} disintegrations per second.

(6) "Adult" means an individual 18 or more years of age.

(7) "Agreement State" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(8) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(9) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of licensed material, exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I, column 3, to 10 CFR Part 20.1001 to 20.2401; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(10) "ALARA" (acronym for "As Low As Reasonably Achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

(11) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(12) "Annual" means occurring every year or within a consecutive twelve month cycle.

(13) "Annual Limit on Intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man that ~~would~~could result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix B, Table I, Columns 1 and 2, to 10 CFR Part 20.1001 to 20.2401.

(14) "As Low As Reasonably Achievable" see "ALARA."

(15) ―Authority" means the Oregon Health Authority.

(16) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive or special nuclear materials regulated by the Authority.

(17) "Becquerel" (Bq) means the International System of Units (SI) unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

(18) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations, of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

(19) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(20) "Byproduct material" means:

(a) Any radioactive material, except special nuclear material, yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction process. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition.

(21) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year must begin in January and subsequent calendar quarters must be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant may change the method observed for determining calendar quarters except at the beginning of a calendar year.

(22) "Calibration" means the determination of:

(a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(b) The strength of a source of radiation relative to a standard.

(23) "CFR" means Code of Federal Regulations.

(24) "Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

(25) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For purposes of these rules, "lung class"

or "inhalation class" are equivalent terms. Materials are classified as D, W, or Y, which applies to a range of clearance half-times:

(a) For Class D, Days, of less than 10 days;

(b) For Class W, Weeks, from 10 to 100 days; and

(c) For Class Y, Years, of greater than 100 days.

(26) "Clinical laboratory" means a laboratory licensed pursuant to ORS 438.110 through 438.140.

(27) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(28) "Committed dose equivalent" ($H_{T,\,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(29) "Committed effective dose equivalent" ($H_{E,\,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,\,50} = \sum W_T, H_{T,50}$).

(30) "Contamination" (Radioactive) means deposition or presence of radioactive material in any place where it is not desired, and particularly in any place where its presence can be harmful. The harm may be in compromising the validity of an experiment or a procedure, or in being a source of danger to persons. Contamination may be divided into two types: Fixed and removable. Removable contamination may be transferred easily from one object to another by light rubbing or by the use of weak solvents such as water or alcohol. Removable contamination is evaluated and recorded in units of microcuries or dpm. Fixed contamination is not easily transferred from one object to another and requires mechanical or strong chemicals to remove it from its current location. Fixed contamination is evaluated and recorded in units of mR/hr.

(31) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations or transformations per second (dps or tps).

(32) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(33) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits:

(a) Release of the property for unrestricted use and termination of license; or

(b) Release of the property under restricted conditions and termination of the license.

(34) "Deep dose equivalent" (H_d) which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(35) "Depleted uranium" means source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(36) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B to 10 CFR Part 20.1001 to 20.2401.

(37) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(38) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

(39) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem (see "Rem"). (See OAR 333-100-0070(2) for SI equivalent sievert.)

(40) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

(41) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

(42) "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = W_T H_T$).

(43) "Electronic product" means any manufactured product or device or component part of such a product or device that is capable of generating or emitting electromagnetic or sonic radiation such as, but not limited to, X-rays, ultrasonic waves, microwaves, laser light or ultraviolet light.

(44) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(45) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(46) "Exclusive use" (also referred to in other regulations as "sole use" or "full load") means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.

(47) "Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(48) "Exposure" means:

(a) The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram.

(b) Being exposed to ionizing radiation or to radioactive material.

(49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute (R/min) and milliroentgen per hour (mR/hr).

(50) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

(51) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(52) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(53) "Fixed gauge" means a measuring or controlling device that is intended to be mounted at a specific location, stationary, not to be moved, and is not portable.

(54) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(55) "General license" means a license granted by rule, in contrast to an issued license, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(56) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(57) "Gray" (Gy) means the International System of Units (SI), unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad). (See OAR 333-100-0070(2))

(58) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

(59) "Healing arts" means:

(a) The professional disciplines authorized by the laws of this state to use X-rays or radioactive material in the diagnosis or treatment of human or animal disease. For the purposes of this ~~Authority~~division they are Medical Doctors, Osteopaths, Dentists, Veterinarians, Chiropractors, and Podiatrists; or

(b) Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition.

(60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(61) "Individual" means any human being.

(62) "Individual monitoring" means:

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(63) "Individual monitoring devices" 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 personal ("lapel") air sampling devices.

(64) "Inhalation class" (see "Class").

(65) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Authority.

(66) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(67) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(68) "Ionizing radiation" means any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. It includes any or all of the following: Alpha particles, beta particles, electrons, positrons, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, fission fragments and other atomic and subatomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(69) "Laser" means any device which, when coupled with an appropriate laser energy source, can produce or amplify electromagnetic radiation by the process of controlled stimulated emission.

(70) "License" means a license issued by the Authority in accordance with rules adopted by the Authority.

(71) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license granted or issued by the Authority. For the purpose of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), Naturally Occurring and Accelerator Produced Radioactive Material (NARM) refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

(72) "Licensee" means any person who is licensed by the Authority in accordance with these rules and the Act.

(73) "Licensing state" means any state with rules or regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of NARM.

(74) "Limits" (dose limits) means the permissible upper bounds of radiation doses.

(75) "Lost or missing licensed or registered source of radiation" means licensed or registered source(s) of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(76) "Lung class" (see "Class").

(77) "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in division 118 of this chapter.

(78) "Member of the public" means an individual, except when that individual is receiving an occupational dose.

(79) "Minor" means an individual less than 18 years of age.

(80) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(81) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

(82) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(83) "Naturally-occurring radioactive material" (NORM) means any nuclide that is found in nature as a radioactive material (i.e., not technologically produced).

(84) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(85) "Natural uranium" means a mixture of the uranium isotopes 234, 235 and 238 (approximately 0.7 weight percent uranium- 235 and the remainder by weight essentially

uranium-238), found in nature, that is neither enriched nor depleted in the isotope uranium 235.

(86) "Nonstochastic effect" means a health effect that varies with the dose and a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

(87) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material". See "Special form."

(88) "NRC" is the acronym for Nuclear Regulatory Commission.

(89) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(90) "Package" means the packaging together with its radioactive contents as presented for transport.

(91) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV.

(92) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

(93) "Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual. See "Individual monitoring devices."

(94) "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(95) "Physician" means an individual licensed by the ~~Oregon State Board of Medical Examiners~~Oregon Medical Board to dispense drugs in the practice of medicine.

(96) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(97) "Portable gauge" means a measuring or controlling device that is intended to be portable and is not fixed to a specific location. All portable gauges require a specific

license (there is no general license granted for portable generally licensed devices in the State of Oregon).

(98) "Program" means the Radiation Protection Services section of the Public Health Division of the Oregon Health Authority.

(99) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below $130^{O}F$ ($54.4^{O}C$).

(100) "Pyrophoric solid" means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

(101) "Qualified expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual must:

(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual must have performed the tasks required of a qualified expert during the year of work experience; or

(c) Receive approval from the Authority for specific activities.

(102) "Quality factor" (Q) means the modifying factor (listed in Tables 1004(b).1 and 1004(b).2 of 10 CFR Part 20.1004 provided at the end of this division) that is used to derive dose equivalent from absorbed dose.

(103) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(104) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray). See OAR 333-100-0070(2) for SI equivalent gray.

(105) "Radiation" means:

(a) Ionizing radiation including gamma rays, X-rays, alpha and beta particles, protons, neutrons, and other atomic or nuclear particles or rays;

(b) Any electromagnetic radiation which can be generated during the operations of electronic products and which the Authority has determined to present a biological hazard to the occupational or public health and safety but does not include electromagnetic radiation which can be generated during the operation of an electronic product licensed by the Federal Communications Commission;

(c) Any sonic, ultrasonic or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and which the Authority has determined to present a biological hazard to the occupational or public health and safety.

(106) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(107) "Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

(108) "Radiation safety officer" means:

(a) An individual who has the knowledge, responsibility, and authority to apply appropriate radiation protection rules; or

(b) The representative of licensee management, authorized by the Authority, and listed on the specific license as the radiation safety officer, who is responsible for the licensee's radiation safety program.

(109) "Radioactive material" means any solid, liquid, or gas that emits radiation spontaneously.

(a) Radioactive material, as used in these rules, includes: byproduct material, naturally occurring radioactive material, accelerator produced material, and source material, as defined in this rule.

(b) Radioactive material, as used in these rules, does not include special nuclear material.

(110) "Radioactive waste" means radioactive material that is unwanted or is unusable, as defined in division 50 of chapter 345. No radioactive material may be disposed of in Oregon except as provided in division 50 of chapter 345.

(111) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

(112) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(113) "Registrant" means any person who is registered with the Authority and is legally obligated to register with the Authority pursuant to these rules and the Act.

(114) "Registration" means the identification of any material or device emitting radiation, and the owner of such material or device must furnish information to the Authority in accordance with the rules adopted by the Authority.

(115) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

(116) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

(117) "Research and development" means:

(a) Theoretical analysis, exploration, or experimentation; or

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(118) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(119) "Restricted area" means an area to which access is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(120) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} Coulombs/kilogram of air (see "Exposure" and division 120).

(121) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

(122) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.

(123) "Sealed source" means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(124) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

(125) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter.

(126) "SI" means the abbreviation for the International System of Units.

(127) "Sievert" means the International System of Units (SI), unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem). (See OAR 333-100-0070(2)).

(128) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(129) "Source material" means:

(a) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(b) Ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

(130) "Source material milling" means any activity that result~~s~~ in the production of byproduct material, as defined by this rule.

(131) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation. Source of radiation, pursuant to this rule, includes, but is not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material sealed and unsealed form (normal form and special form), and radioactive material uses.

(132) "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31. 1996, and constructed prior to April 1, 1998, may continue to be used. Any other special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

(133) "Special nuclear material" means:

(a) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(134) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination must not exceed one.

For example, the following quantities in combination ~~would~~does not exceed the limitation and are within the formula: * * ~~(~~175 (grams ~~contained~~ U-235)/350 + ~~(~~50 (grams U-233)/200 + ~~(~~50 (grams Pu)/200 = 1.

(135) "Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(136) "Stochastic effect" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(137) "Supervision" as used in these rules, means the responsibility for, and control of, the application, quality, radiation safety and technical aspects of all sources of radiation possessed, used and stored through authorization granted by the Authority.

(138) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

(139) "Termination" means:

(a) The end of employment with the licensee or registrant or, in the case of individuals not employed by the licensee or registrant, the end of work assignment in the licensee's or registrant's restricted area in a given calendar quarter, without expectation or specific scheduling of re-entry into the licensee's or registrant's restricted area during the remainder of that calendar quarter; or

(b) The closure of a registered or licensed facility and conclusion of licensed or registered activities, pursuant to a registration or specific license.

(140) "Test" means the process of verifying compliance with an applicable rule.

(141) "These rules," mean all parts of the Oregon Administrative Rules promulgated under ORS 453.605 through 453.807.

(142) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(143) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent (DDE) and the committed dose equivalent (CDE) to the organ receiving the highest dose as described in OAR 333-120-0650(1)(d).

(144) "Transport index" means the dimensionless number (rounded up to the first decimal place) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

(145) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

(146) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

NOTE: "Ore" refers to fuel cycle materials pursuant to 10 CFR Part 150.

(147) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

(148) "Uranium — depleted, enriched" means:

(a) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(b) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(149) "Validation certificate" means the official document issued upon payment to the Authority of the appropriate fee listed in division 103 of this chapter. The license or registration is subject and void without the annual validation certificate.

(150) "Waste" means radioactive waste.

(151) "Week" means seven consecutive days starting on Sunday.

(152) "Weighting factor" (W_T) for an organ or tissue (T) means:

(a) The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

(A) Gonads 0.25;

(B) Breast 0.15;

(C) Red Bone Marrow 0.12;

(D) Lung 0.12;

(E) Thyroid 0.03;

(F) Bone Surfaces 0.03;

(G) Remainder 0.30 (see note below);

(H) Whole Body 1.00.

Note: Assignment of 0.30 for the remaining organs results from a weighting factor of 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

(b) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $W_T = 1.0$, has been specified. The use of other weighting factors for external exposure ~~will~~may be approved on a case-by-case basis until such time as specific guidance is issued.

(153) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(154) "Worker" means an individual engaged in work under a license or registration issued by the Authority and controlled by a licensee or registrant, but does not include the licensee or registrant.

(155) "Working level" (WL) means any combination of short-lived radon progeny in one liter of air that will result in the ultimate emission of 1.3 x 105 MeV of potential alpha particle energy. The short-lived radon-222 progeny are: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220 the progeny are: polonium-216, lead-212, bismuth-212, and polonium-212.

(156) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(157) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[ED. NOTE: Tables and Appendices referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

General Licenses - Radioactive Material other than Source Material

333-102-0115

Certain Measuring, Gauging and Controlling Devices

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR 333-103-0015 and sections (2), (3) and (4) of this rule, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in section (1) of this rule applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Authority pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(i) of this rule.

NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:

(a) Must assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and must comply with all instructions and precautions provided by such labels;

(b) Must assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta ~~and/~~or gamma -emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding an applicable specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.

(d) Must maintain records showing compliance with the requirements of subsections (4)(b) and (4)(c) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(A) Records of tests for leakage of radioactive material required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(B) Records of tests of the on-off mechanism and indicator required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(C) Records which are required by subsection (4)(c) of this rule must be maintained as required in OAR 333-100-0057.

(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee must immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific

license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Authority. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be submitted to the Authority within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Authority, on a case-by-case basis;

(f) Must not abandon the device containing radioactive material;

(g) Except as provided in subsection (4)(i) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(l) of this rule, by transfer to another general licensee as authorized in subsection (4)(i) of this rule, or by transfer to a specific licensee of the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes the individual to receive the device; and

(A) Must furnish to the Authority, within 30 days after transfer of a device to a specific licensee or export, a report containing identification of the device by manufacturer's name, model number, serial number, the date of transfer, and the name, address and license number of the person receiving the device;

(B) The general licensee must obtain written Authority approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.

(h) A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(A) Verifies that the specific license authorized the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label so that the device is labeled in compliance with OAR 333-120-0430, however the manufacturer model and serial numbers must be retained;

(C) Obtains manufacturer's or initial transferor's information concerning maintenance that are~~would be~~ applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).

(i) Must transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor must give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Authority the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the date of transfer, the name and address of the transferee and the location of use, and the name, title and phone number of the individual who is a point of contact between the Authority and the transferee. This individual must have the knowledge and authority to take actions to ensure compliance with the appropriate rules and requirements concerning the possession and use of these devices; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(j) Must comply with the provisions of OAR 333-120-0700 and 333-120-0710 for reporting radiation incidents, theft or loss of licensed material but shall be exempt from the other requirements of divisions 111 and 120 of this chapter;

(k) Must submit the required Authority form and receive from the Authority a validated registration certificate acknowledging the general license and verifying that all provisions of these rules have been met. The form must be submitted within 30 days after the first receipt or acquisition of such device. The general licensee must develop and maintain procedures designed to establish physical control over the device as described in this rule and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices.

(l) Shall not export a device containing radioactive material except in accordance with 10 CFR Part 110.

(5) The general license in section (1) of this rule does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0335, 333-103-0015 and 333-118-0050.

(7) The general licensee possessing or using devices licensed under the general license established by section (1) of this rule must report in writing to the Authority any changes in information furnished by the licensee on the required Authority form. The report must be submitted within 30 days after the effective date of such change.

(8) The licensee must appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and

requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(9)(a) A device distributed or otherwise received as a generally licensed device must be registered with the Authority. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee. Devices containing more than 37 MBq (1 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241, 3.7 MBq (0.1 mCi) of radium 226 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label are required to have a specific license.

(b) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Authority:

(A) Name and mailing address of the general licensee;

(B) Information about each device. The manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under section (8) of this rule.

(D) Address or location at which the device(s) are used and~~/or~~ stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(10) General licensees must report changes to their mailing address or the location of use (including a change in name of general licensee) to the Authority within 30 days of the effective date of the change.

(11) Generally licensed devices that are not in use for longer than two years must be transferred to an authorized recipient or disposed of as radioactive waste. Shutters must be locked in the closed position on devices that are not being used or are in storage. The testing required by subsection (4)(b) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in section (9) of this rule are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 consecutive days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.

(13) The general license in section (1) of this rule does not authorize the manufacture or import of devices containing radioactive material.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

Specific Licenses

333-102-0203

Definitions

The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:

NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.

(1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe, etc. samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.

(2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.

(3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by 333-103-0010(2)(m)), or other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.

(4) "Beneficiating" means subjecting a product to any process that can~~will~~ increase or concentrate any component (including the radioactive materials) to benefit the product.

(5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with 333-116-0420. Brachytherapy includes radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.

(6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.

(7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.

(8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.

(9) "Commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that can~~would~~ adversely affect the natural environment of a site.

(10) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

(11) "Decontamination and Decommissioning" means:

(a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and

(b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.

(12) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

(13) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.

(14) "Exempt Source" means radioactive material, exempt from the rules in this chapter.

(15) "Facility" means location of licensed activities under the direct control of licensee management. If a "facility," as used in this division, includes multiple separate addresses, the Authority may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.

(16) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-ray & Hybrid Gauges pursuant to division 115 of this chapter, that contain either an X-ray source or a radioactive sealed source.

(17) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(18) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0103.

(19) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.

(20) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.

(21) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.

(22) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.

(23) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.

(24) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed;

conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.

(25) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.

(26) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.

(27) "Generators and Kits" means "Imaging and Localization."

(28) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.

(29) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.

(30) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an X-ray source, pursuant to division 115 of this chapter.

(31) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by 333-102-0130(2).

(32) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-0800 through 333-116-0880.

(33) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.

(34) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.

(35) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product

or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.

(36) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.

(37) "Irradiator Self-shielded or Other -- Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.

(38) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

(39) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that can~~should~~ be accepted.

(40) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.

(41) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.

(42) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (13) and (41) of this rule and require separate specific licenses for each activity.

(43) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.

(44) ~~"~~Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR 20 Appendix E.

(45) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05 percent~~%~~ source material.

(46) "Net working capital" means current assets minus current liabilities.

(47) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

(48) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.

(49) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.

(50) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(r~~n~~) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR chapter 345, division -050. Any material that contains NORM requires a specific license unless exempted in OAR chapter 345, division -050. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.

(51) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).

(52) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.

NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license ~~should~~ specifies~~y~~ which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.

(53) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).

(54) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.

(55) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.

NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).

(56) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by OAR 333-116-0800 and included in the facility specific license issued pursuant to 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.

(57) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.

(58) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.

(59) "Principal Activities" means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(60) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (e.g., breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").

(61) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).

(62) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.

(63) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to OAR 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.

(64) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with 333-116-0360.

(65) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.

(66) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to 333-103-0010 and 333-103-0015.

(67) "Responsible Representative" means

(a) The person designated as having responsibility for general license device or general license material;

(b) The person management has selected to certify general license inventory; and

(c) The individual responsible to the Authority and to management to ensure that all regulatory elements are adequate.

(68) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.

NOTE: The Authority no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.

(69) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(70) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with 333-116-0400.

(71) "Special Nuclear Material" means:

(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(72) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be annotated on the specific license, and validated with a specific license fee pursuant to 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").

(73) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

(74) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets may~~would~~ not include intangibles such as goodwill and rights to patents or royalties.

(75) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

(76) "Temporary Job Site" means any location, where specific license material is used that is either:

(a) Not the specific location of the licensee if an in-state licensee; or

(b) Any location in the s~~S~~tate if an out-of-state specific licensee pursuant to a specific radioactive materials license.

NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.

(77) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

(78) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to a~~A~~gencies in the Oregon Health Authority.

(79) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in 333-116-0300 for uptake, dilution, and excretion studies.

(80) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.

NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.

(81) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to OAR 333-116-0280.~~;~~

(82) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.

(83) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.

NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities,
Products or Devices Which Contain Radioactive Material

333-102-0250

Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License

~~Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License~~

An application for a specific license to manufacture or distribute radioactive material for use under the general license specified in OAR 333-102-0130 or equivalent may~~will~~ be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200.~~;~~

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Carbon-14 in units not exceeding ten microcuries (370 kBq) each;

(b) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each;

(c) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(d) Iodine-125 in units not exceeding ten microcuries (370 kBq) each;

(e) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;

(f) Iodine-131 in units not exceeding ten microcuries (370 kBq) each;

(g) Iron-59 in units not exceeding 20 microcuries (740 kBq) each;

(h) Selenium-75 in units not exceeding ten microcuries (370 kBq) each;

(i) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185

Bq) of americium-241 each or colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and;

(b) Displaying the radiation caution symbol described in OAR 333-120-0400 and the words, CAUTION, RADIOACTIVE MATERIAL and Not for Internal or External Use in Humans or Animals.

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(b) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements in OAR 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0285

Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Radioactive Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter may~~will~~ be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant submits evidence that the applicant is at least one of the following:

(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(B) Registered or licensed with a state agency as a drug manufacturer;

(C) Licensed as a pharmacy by a state Board of Pharmacy;

(D) Operating as a nuclear pharmacy within a federal medical institution; or

(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radiopharmaceutical drugs by medical use licensees; and

(d) The applicant satisfies the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceutical drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL~~"~~ and an identifier that ensures that the syringe,

vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:

(a) May prepare radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b~~e~~) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

(B) This individual meets the requirements specified in OAR 333-116-0910, 333-116-0760, 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(d) of this rule.

(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in OAR 333-116-0020) as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radiopharmaceutical drugs containing accelerator-produced radioactive material; and

(B) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulator Commission.

(e) Shall provide to the Authority a copy of:

(A) Each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910 with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or

(B) The Commission or Agreement State license; or

(C) Commission master materials licensee permit; or

(D) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(E) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) A copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows pursuant to paragraphs (2)(b)(A) and (2)(b)(C) of this rule, which allows the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceutical drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceutical drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this rule relieves the licensee from complying with applicable FDA, other federal~~,~~ and state requirements governing radiopharmaceutical drugs.

NOTE: Although the Authority does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the Authority for use by persons licensed for medical use pursuant to OAR chapter 333, division ~~-~~116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory Commission or any other Agreement State, may submit the pertinent information specified in this rule.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0340

Reciprocal Recognition of Licenses

(1) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or a licensing state, and issued by the Authority having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 consecutive days in any calendar year, provided that:

(a) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) The out-of-state licensee has notified the Authority using the Notification of Entry to Perform Activities Under Oregon Reciprocity Application form at least three days prior to engaging in such activity and has paid the applicable registration fee pursuant to OAR 333-103-0030. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period ~~would~~ imposes an undue hardship on the out-of-state licensee, the licensee may, upon application to the Authority, obtain permission to proceed sooner. The Authority may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license granted by subsection (1)(a) of this rule;

(c) The out-of-state licensee complies with all applicable rules of the Authority and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the Authority or laws of the State of Oregon;

(d) The out-of-state licensee supplies such other information as the Authority may request; and

(e) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in subsection (1)(a) of this rule except by transfer to a person:

(A) Specifically licensed by the Authority or by the U.S. Nuclear Regulatory Commission to receive such material; or

(B) Exempt from the requirements for a license for such material under OAR 333-102-0010(2).

(2) Notwithstanding the provisions of section (1) of this rule, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to 10 CFR 31.6 or equivalent regulations of an Agreement State, authorizing the holder of the license to manufacture, transfer, install or service a device described in OAR 333-102-0115(1) within the State of Oregon is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:

(a) Such person shall register the general license pursuant to OAR 333-101-0007;

(b) File a report with the Authority within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;

(c) Ensure that the device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

(d) Ensure that any labels required to be affixed to the device under rules of the licensing authority also include the statement "Removal of this label is prohibited"; and

(e) The holder of the specific license shall furnish to each general licensee to whom such device is transferred, or on whose premises such a device is installed, a copy of the general license contained in OAR 333-102-0115 or in equivalent rules of the Authority having jurisdiction over the manufacture and distribution of the device.

(3) The Authority may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property. The Authority may deny the licensee to perform activities under Oregon reciprocity.

(4) The out-of-state licensee shall at all times during work at any work location within the state have available the pertinent licensing document, the applicable sections of the State of Oregon radiation regulations, a complete source inventory, pertinent U.S. Department of Transportation documentation, leak test records, instrument calibration records, personnel training records, and necessary documentation required by applicable special requirements of these regulations.

(5) While working in Oregon, the out-of-state licensee shall notify the Authority (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (bankruptcy) of the United States code by or against:

(a) The licensee;

(b) An entity (as that term is defined in II U.S.C 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in II U.S.C. 101(2)) of the license.

(6) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to this rule, each day worked at each location shall count toward the limit of 180 consecutive days in a calendar year.

(7) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule, based upon an acceptable licensing document, will receive acknowledgment from the Authority. This acknowledgment shall be kept at the site of use.

(8) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule based upon an acceptable licensing document is subject to the reciprocity fee and may be inspected by the Authority. The fee for the general license granting reciprocity shall:

(a) Be charged as provided by division 103 of this chapter; and

(b) Shall not be charged more often than once during each calendar year.

(9) Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 106

X-RAYS IN THE HEALING ARTS

General Requirements

333-106-0045

Use of Best Procedures and Equipment

Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include, but is not limited to:

(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see Tables 1, 2 and 3. The referenced tables are available on the Program's website: ~~http://oregon.gov/DHS/ph/rps/index.shtml~~www.healthoregon.org/rps.

(3) Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation due to the medical status of the patient or the inability of the patient to be left alone during the imaging procedure except as permitted under section (4) of this rule.

(4) Hand-held dental units may be used at facilities or programs as defined in ORS 680.205(1) and (2).

(5) X-ray systems subject to OAR 333-106-0301(1) shall not be utilized in procedures where the source to patient distance is less than 30 centimeters (cm).

(6) Cardboard cassettes without screens shall not be used (dental intraoral excluded).

(7) The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the clinical condition.

(8) Use of techniques designed to compensate for anatomical thickness variations after the primary beam has exited the patient is specifically prohibited. This includes "split screen" imaging techniques whereby multiple speed intensifying screens are placed in the same cassette, or any techniques which rely on attenuation of secondary (remnant) radiation for compensatory purposes. Lead lined grids, which are designed to reduce scattered radiation are excluded from this provision.

(9) Filter slot covers shall be provided for the X-ray operator's protection.

(10) Facilities shall determine or cause to be measured the typical patient exposure for their most common radiographic examinations. The exposures shall be recorded as milliroentgens measured in free air at the point of skin entrance for an average patient. These exposure amounts must then be compared to existing guidelines and rules, and if they exceed such guidelines or rules, action must be taken to reduce the exposure while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted in the radiographic examination rooms so that they are readily available to administrators, X-ray operators, patients and practitioners.

(11) Protective equipment including aprons, gloves and shields shall be checked annually for defects, such as holes, cracks and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Authority. If such defect is found, equipment shall be replaced or removed from service until repaired. Fluoroscopy

shall only be used for this purpose if a visual and manual check indicated a potential problem.

(12) Dental X-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.

(13) An X-ray quality control program shall be implemented when required by the Authority.

(14) All X-ray equipment must be capable of functioning at the manufacturer's intended specifications.

(15) All patients' radiographic images or copies shall be made available for review by any practitioner of the healing arts, currently licensed by the appropriate Oregon licensing board, upon request of the patient.

(16) Requirements for the operation of fluoroscopic X-ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:

(a) Radiologists;

(b) Non-Radiologist practitioners with proper training in the operation and use of fluoroscopic X-ray equipment;

(c) R.T.s, must be ARRT registered and in good standing with the Oregon Board of Medical Imaging.~~OBRT~~;

(d) R.P.A.s and R.R.A.s;

(e)~~ Technologists, who have successfully completed an OBRT approved program in radiologic technology as defined in ORS 688.405, may temporarily operate fluoroscopic equipment while waiting to take the A.R.R.T. registry examination~~: Technologists, who have successfully completed an educational program in radiologic technology from an approved school as defined in ORS 688.405 may temporarily operate fluoroscopic equipment for up to one year as outlined in OAR 337-010-0045 while waiting to take the ARRT registry examination.

(A) The temporary period ~~will~~ expires when the individual has passed the registry examination and is considered an R.T.; or

(B) One year from the date when the technologist completed his/~~-~~her training, provided; and

(C) The technologist, while in the temporary status referred to in subsection (16~~5~~)(e) of this rule, has a current temporary license issued by the Oregon Board of Medical Imaging.~~OBRT~~.

(f) The operation of fluoroscopic equipment by R.T.s, or R.P.A.s or R.R.A.s shall be performed under the supervision of a radiologist and is restricted to the healing arts exclusively for the purpose of localization and~~/or~~ to assist physicians in obtaining images for diagnostic purposes.

(g) Where direct or indirect supervision by a radiologist is impractical, a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment is permitted to supervise an R.T. operating fluoroscopic equipment provided that the registrant arranges to have a radiologist or Medical or Health physicist to assist in;

(A) Developing fluoroscopic and radiation safety policies and procedures;

(B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and

(C) At least annually, review the registrant's fluoroscopy program. The review ~~should~~ includes an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.

(h) The operation of fluoroscopic equipment by a R.T. is restricted to the healing arts exclusively for the purpose of localization and~~/or~~ to assist physicians in obtaining images for diagnostic purposes.

(i) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405, may only operate fluoroscopic equipment under the direct supervision of a Radiologist or a R.T. while in the clinical phase of training.

(j) Students currently enrolled in an Authority approved R.P.A. or R.A. training program, may only operate fluoroscopic equipment under the direct or in-direct supervision of a Radiologist during their clinical phase of training.

(k) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.

(l) Proper training in the operation of fluoroscopic X-ray equipment shall include but not be limited to the following:

(A) Principles and operation of the fluoroscopic X-ray machine;

(i) Generating X-rays;

(ii) kVp and mA;

(iii) Image intensification;

(iv) High level control versus standard operating mode;

(v) Magnification (multi-field);

(vi) Automatic Brightness Control (ABC);

(vii) Pulsed versus Continuous X-ray Dose Rates;

(viii) Image recording modes;

(ix) Imaging Systems (TV and Digital);

(x) Contrast, noise and resolution;

(B) Radiation units;

(i) Traditional units;

(ii) SI units;

(iii) Dose Area Product;

(C) Typical fluoroscopic outputs;

(i) Patient skin entrance dose;

(ii) Standard Roentgen per minute (R/min) dose rates;

(iii) High level/Boost enable Roentgen per minute (R/min) dose rates;

(D) Dose reduction techniques for fluoroscopy;

(i) The use of collimation;

(ii) X-ray tube and Image intensifier placement;

(iii) Patient size versus Technique selection;

(iv) Use of grid;

(v) Use of last image hold;

(vi) Additional beam filtration;

(vii) Alternate gantry angles;

(viii) Use of spacer cone;

(ix) Pulsed fluoroscopy;

(E) Factors affecting personnel dose;

(i) Patient dose;

(ii) Scatter radiation;

(iii) Tube and Image intensifier placement;

(iv) Time, distance and shielding;

(F) Protective devices;

(i) Lead aprons and gloves;

(ii) Thyroid collars;

(iii) Protective glasses;

(iv) Leaded drapes;

(v) Bucky slot cover;

(vi) Protective shields/barriers;

(G) Radiation exposure monitoring;

(i) Personnel monitors;

(ii) Placement of personnel monitors;

(iii) Occupational and non-occupational dose limits;

(H) Biological effects of X-ray radiation;

(i) X-rays and particulate matter;

(ii) Absorption variables (field size, dose rate, etc.);

(iii) Scatter radiation;

(iv) Cell sensitivity;

(v) Acute effects;

(vi) Latent effects;

(I) Applicable regulations;

(i) Federal; and

(ii) Oregon Rules for the Control of Radiation to include, but not limited to, divisions 101, 103, 106, 111 and 120.

(17) Radiologists, R.A.s or R.P.A.s and R.T.s currently licensed in Oregon are considered to have met the training requirements in subsection (16~~5~~)(l) of this rule.

(18) Fluoroscopic equipment operators who qualified to operate fluoroscopic X-ray equipment prior to April 11, 2005, are~~will be~~ considered as having met the training requirements in subsection (16~~5~~)(l) of this rule.

(19) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.As and R.P.As may issue a preliminary report, however, the final report must be issued by their supervising radiologist.

(20) Written procedures for fluoroscopic X-ray equipment operators shall be available at the worksite and include:

(a) A list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;

(b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;

(c) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;

(d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and

(e) The name and title of the individual who is responsible for the direction of R.T.s who operate fluoroscopic equipment.

(21) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(7~~8~~) ~~of these rules~~ using measurement protocol in compliance with OAR 333-106-0210 ~~of these rules~~ and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.

(22) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patients name, the type of examination, the date of the examination, the fluoroscopists name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on time for each fluoroscopic examination and:

(a) No later than May 1, 2006, establish cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:

(A) Routine procedures performed on adults;

(B) Routine procedures performed on children;

(C) Orthopedic procedures performed in surgery;

(D) Urologic procedures performed in surgery;

(E) Angiographic procedures performed;

(F) Interventional cardiac studies.

(b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;

(c) Take appropriate action, when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmarks established by the facility for a particular procedure more than ten percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions ~~should~~, at a minimum, include;

(A) Notification of the individual; and

(B) Recommendation that the individual undergo additional coaching, training, etc. in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0101

Diagnostic X-ray Systems

~~Additional Requirements.~~ In addition to other requirements of this division, all diagnostic X-ray systems shall meet the following requirements:

(1) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) The state shall~~will~~ attach an identification number to each X-ray control panel or an appropriate location:

(a) Identification numbers shall not be removed without written permission of the Authority;

(b) Identification numbers shall not be defaced.

(3) Mobile and portable X-ray systems shall meet the requirements of a stationary system when used for greater than seven consecutive days in the same location.

(4) Battery Charge Indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(5) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 mR (25.8 C/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(6) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not

exceed 2 mR (0.516 C/kg) in one hour at 5 cm from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(7) Beam Quality:

(a) Half-Value Layer (HVL):

The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table 4. If it is necessary to determine such HVL at an X-ray tube potential which is not listed in Table 4, linear interpolation or extrapolation may be made; The referenced table is available on the Program's website: www.healthoregon.org/rps~~http://www.oregon.gov/DHS/ph/rps/index.shtml~~.

(A) The HVL required in subsection (7)(a) of this rule is~~will be~~ considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 5. The referenced table is available on the Program's website: www.healthoregon.org/rps~~http://www.oregon.gov/DHS/ph/rps/index.shtml~~.

(B) In addition to the requirements of section (5) of this rule, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum HVL not less than 1.5 mm aluminum (Al) equivalent filtration permanently installed in the useful beam;

(C) Beryllium window tubes shall have a minimum of 0.5 mm Al equivalent filtration permanently installed in the useful beam;

(D) For capacitor energy storage equipment, compliance with the requirements of section (5) of this rule shall be determined with the maximum quantity of charge per exposure;

(E) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials, which are always, present between the source and the patient.

(b) Filtration Controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by subsection (5)(a) of this rule is in the useful beam for the given kVp, which has been selected.

(8) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes, which have been selected, shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly, which has been selected.

(9) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly ~~will~~ remains stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

(10) Technique Indicators:

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors, which are set prior to the exposure, shall be indicated;

(b) The requirement of subsection (10)(a) of this rule may be met by permanent marking on equipment having fixed technique factors.

(11) There shall be provided for each X-ray machine a means for determining the proper SID.

(12) X-ray film developing requirements. Compliance with this section is required of all healing arts registrants and is designed to ensure that patient and operator exposure is minimized and to produce optimum image quality and diagnostic information:

(a) Manual processing of films.

(A) The relationship between temperature of the developer and development time indicated in Table 6 or the manufacturer's recommendations must be used with standard developing chemistry. The referenced table is available on the Program's website: www.healthoregon.org/rps~~http://www.oregon.gov/DHS/ph/rps/index.shtml~~.

(B) Processing of film. All films shall be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if:

(i) Film manufacturer's published recommendations for time and temperature are followed; or

(ii) Each film is developed in accordance with the time-temperature chart (see subsection (12)(a) of this rule).

(C) Chemical-film processing control.

(i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations;

(ii) Developer replenisher shall be periodically added to the developer tank based on the recommendations of the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.

(D) All processing chemicals shall be completely replaced at least every two months or as indicated by the manufacturer.

(E) Devices shall be available which will:

(i) Give the actual temperature of the developer; and

(ii) Give an audible or visible signal indicating the termination of a preset development time (in minutes or seconds).

(b) Automatic film processing. Films shall be processed in such a manner that the degree of film development is the same as ~~would~~ being achieved by proper adherence to subsection (12)(a) of this rule (manual processing).

(c) Darkrooms. Darkrooms shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through an appropriate safelight filter.

(d) Safelights shall be mounted in accordance with manufacturer's recommendations.

(e) Light bulbs used in safelights shall be the type and wattage recommended by the manufacturer.

(f) Safelight lenses shall be the type recommended for use by the film manufacturer.

(g) Rapid film processing. Special chemicals have been designed for use in Endodontics. These chemicals have special development requirements and do not permit as large of a margin of error in darkroom technique as do standard developing chemicals. Failure to precisely follow manufacturer's recommendations can easily lead to overexposure and underdevelopment. Darkroom procedures shall include:

(A) The manufacturer's time temperature development is crucial and shall be followed exactly;

(B) Caution: A timer capable of accurately measuring the short development times required shall be used;

(C) If rapid chemical processing is used for general radiography all applicable requirements of section (12) of this rule shall be followed.

(h) The Authority shall make such tests as may be necessary to determine compliance with this section.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

Radiographic Systems other than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography X-ray Systems

333-106-0305

Radiation Exposure Control Devices

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;

(b) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.

(2) X-ray Exposure Control:

(a) An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(A) Exposure of 0.5 second or less; or

(B) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Each X-ray exposure control shall be located in such a way as to meet the following requirements:

(A) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(B) The operator's protected area shall provide visual indication of the patient during the X-ray procedure; and

(C) Mobile and portable X-ray systems which are:

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph (2)(b)(A) of this rule;

(ii) Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of subparagraph (2)(b)(C)(i) of this rule or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or

(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of subparagraph (2)(b)(C)(i) or (ii) of this rule or be provided with a method of X-ray control which ~~will~~ permits the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

(c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic Exposure Controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) The minimum exposure time for all equipment other than that specified in subsection (3)(b) of this rule shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subsection (3)(d) of this rule, and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four timer tests are performed: (T)$\geq$~~>/~~ 5 (Tmax - Tmin).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0315

Exposure Reproducibility

The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five~~5~~ times the maximum exposure (Emax) minus the minimum exposure (Emin). E ≥~~>/~~ 5 (Emax - Emin).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0325

Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101~~ of these rules~~, the requirements of this rule apply to X-ray equipment and facilities where intraoral dental radiography is conducted. Requirements for extraoral dental radiographic systems are covered in OAR 333-106-~~-~~0301 through 333-106-0320~~ of these rules~~. Intraoral dental radiographic systems must meet the following requirements:

(1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

(a) 18 cm if operable above 50 kVp; or

(b) 10 cm if operable at 50 kVp only.

(2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or

(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:

(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off-" position if either position is provided;

(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(d) Exposure termination.

(e) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed:

(T) ≥~~>/~~ 5 (Tmax – Tmin).

(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.

(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".

(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:

(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(80)~~1)(a)(b)~~, and the operator shall remain in that protected area during the entire exposure; and

(b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.

(c) Mobile and portable X-ray systems which are:

(A) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule

(B) Used for less than one week at the same location, i.e., a room or suite, shall be provided with:

(i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or

(ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures; or

(iii) A full length protective apron, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand-held dental intraoral X-ray machine.

(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E ≥ ~~>/~~ 5 (Emax - Emin)

(6) Accuracy.

(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.

(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs on humans.

(7) Administrative Controls:

(a) Patient and film holding devices shall be used when the techniques permit;

(b) The tube housing and the PID shall not be hand held during an exposure;

(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection (2)(a) of this rule or its updated version;

(d) All patients shall be provided with a leaded apron during any dental X-ray exposure;

(e) Dental fluoroscopy without image intensification shall not be used;

(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Authority.

(8) Hand-held X-ray systems.

(a) Registrants must provide for security and safe storage while not in use.

(A) A report must be filed with the Authority within 72 hours if the hand-held unit is lost or stolen.

(b) The image receptor used with hand-held dental X-ray systems must either be:

(A) A speed class of intra-oral film designated as ~~"~~E/F", ~~"~~F" or faster; or

(B) A digitally acquired image (CR or DR).

(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.

(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand-held unit must provide documentation to the Authority of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.

(e) The hand-held unit must be capable of a minimum of 60 kVp and 2.0 mA.

(f) Hand-held units not meeting the requirements of subsections (8)(c), (8)(d) and (8)(e) of this rule may not be sold, distributed or used in the State of Oregon.

(9) Hand-held dental X-ray administrative controls.

(a) The operator must wear a whole body protective apron and thyroid collar of 0.25 mm of lead equivalent when using the unit.

(b) Hand-held units must meet the requirement of OAR 333-106-0045(3).

(A) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.

(B) The unit can~~will~~ only be operated in an enclosed room when possible. All individuals except the X-ray operator and the patient must~~will~~ leave the room and stand behind a protective barrier or be at least six feet from the X-ray source if a protective barrier is not available during radiographic exposures.

(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(14) before using a hand-held unit.

(A) Training on the safe use of the unit shall be documented and include at a minimum:

(i) Proper positioning of the unit to ensure an adequate protected position;

(ii) Limitations on the use of position indicating devices that require longer distances to the patient's face;

(iii) Diagrams (i.e.~~:~~ drawings, illustrations, schematics, etc.) of protected position and location in relationship to the unit;

(iv) Diagrams (i.~~e~~, drawings, illustrations, schematics, etc.) of the effect of improper distance or removal of shielding device; and

(v) Diagrams (i.e. drawings, illustrations, schematics, etc.) of common examples of improper positioning of the unit and or location of the operator.

(d) An appropriate receptor holder must be used during the X-ray exposure.

(e) A PID must be used during the X-ray exposure.

(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

Computed Tomography X-ray Systems

333-106-0370

Operator Requirements

(1) Computed Tomography (CT) X-ray systems shall be operated by individuals who:

(a) Are registered with the American Registry of Radiologic Technologists (A.R.R.T); and

(b) Have received additional CT system training; and

(c) Meet the clinical experience requirements for C~~.~~T~~.~~ established by A.R.R.T.; and

(d) Are currently licensed by the Oregon Board of Medical Imaging.

(2) Individuals who are registered with the A.R.R.T. and credentialed as an R.T. (R) and (CT) are considered to have met the CT training requirement in ~~333-106-0370~~section (1) of this rule and clinical experience requirement in subsection (1)(c~~a~~) of this rule.

(3) Those individuals who have met the requirements of section (1) of this rule prior to the effective date of this rule are considered to have met subsection (1)(a) of this rule.

(4) Technologists operating CT systems must do so under the direction of a radiologist.

(5) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems shall be operated by a technologist licensed by the Oregon Board of Medical Imaging who is:

(a) Any registered radiographer with the credential R.T. (R); or

(b) Registered radiation therapist with the credential R.T. (T);~~ and~~

~~(c) Who are currently licensed by the Oregon Board of Medical Imaging; or~~

(c~~d)~~ Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(d~~e~~) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(6) The individuals mentioned in section (5) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

(7) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority and:

(a) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or

(b) Individuals meeting the requirements of section (5) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (7)(a) of this rule.

(8) R.T. (N)s or CNMTs who have become certified in Computed Tomography through the American Registry of Radiologic Technologists are considered to have met the training requirements in section (5) of this rule.

(9) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320~~ of these rules~~.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0720

Quality Assurance Program

(1) The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic X-ray

imaging system. The quality assurance program shall include the testing required in section (5) of this rule, as well as the evaluation of the test results and corrective actions necessary to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement are as follows:

(a) The registrant shall identify in policy/procedure, by name, a Lead Interpreting Physician meeting the requirements of OAR 333-106-0750(2), whose responsibilities at a minimum must include:

(A) Ensuring that the registrant's quality assurance program meets all associated rules and regulations;

(B) Ensuring that an effective quality assurance program exists;

(C) Providing frequent feedback to mammography technologists regarding film quality and quality control procedures;

(D) Reviewing the Quality Control Technologist's test data at least every three months, or more if consistency has not been shown or problems are evident;

(E) Reviewing the Medical Physicist's annual survey report or equipment evaluation results.

(b) The registrant shall identify in policy/procedure, by name, and have the services of, a Medical Physicist who meets the requirements of OAR 333-106-0750(3). The Medical Physicist shall assist in overseeing the equipment quality assurance practices of the registrant. At a minimum, the Medical Physicist shall be responsible for the annual surveys, mammography equipment evaluations, and associated reports meeting all the requirements of MQSA.

(c) The registrant shall identify in policy/procedure, by name, a single qualified Quality Control Technologist meeting the requirements of OAR 333-106-0750(1), who shall be responsible for:

(A) Equipment performance monitoring functions;

(B) Analyzing the monitoring results to determine if there are problems requiring correction;

(C) Carrying out or arranging for the necessary corrective actions when results of quality control tests including those specified in section (5) of this rule, indicate the need; and

(D) The Quality Control Technologist may be assigned other tasks associated with the quality assurance program that are not assigned to the Lead Interpreting Physician or Medical Physicist. These additional tasks must be documented in written policy/procedure.

(2) Annual Survey. At intervals not to exceed 12 to -14 months, the registrant shall have a Medical Physicist meeting the requirements of OAR 333-106-0750(3) conduct a survey to evaluate the mammography equipment, and the effectiveness of the quality assurance program required in section (1) of this rule. Records of annual surveys shall be maintained for a minimum of two years, and shall be available on-site for Authority review.

(3) Annual survey/or equipment evaluation corrective actions. Corrective action shall be completed within 30 working days of when the registrant received written or verbal notice of recommendations or failures on their annual survey/or equipment evaluation report, unless otherwise noted in these rules or a written request for extension has been submitted to and approved by the Authority.;

(a) Correction of equipment related failures or recommendations shall be demonstrated by a repeat test using the same test methodology and documentation, or a test accepted as the equivalent by the Authority, that was used to initially identify the problem.

(b) When the results of a quality control test/s fail to meet applicable action limits defined in these rules, the appropriate action regarding the suspension or continuation of mammography as defined in these rules or in MQSA, shall be taken.

(4) Quality assurance records. The registrant shall ensure that:;

(a) Records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, policies, previous inspection findings, and radiation protection are maintained until inspected by the Authority.

(b) Quality control monitoring data and records, problems detected by the analysis of that data, corrective actions, and records of the Lead Interpreting Physician's periodic reviews of the Quality Control Technologist's monitoring data taken must be maintained for a minimum of two years.

(5) Equipment quality control tests frequency. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified in Table 7. The referenced table is available on the Program's website: www.healthoregon.org/rpshttp://www.oregon.gov/DHS/ph/rps/index.shtml.

(6) Testing methods and action limits for quality control tests shall meet the most current requirements of MQSA, in addition to the following:;

(a7) Screen/film contact. Screen film contact tests shall be performed on all screens used clinically, using a 40-mesh test tool and four cm thick sheet of acrylic. Screens demonstrating one or more areas of poor contact that are greater than one cm in diameter, that are not eliminated by screen cleaning, and remain in the same location during

subsequent tests, shall not be used for mammography. Screen/film contact shall be such that any areas of poor contact, regardless of size, shall not detract from image quality.

(b~~8~~) Processor performance. A processor performance test shall be performed by sensitometric means and evaluated daily, after the solution temperature in the processor has reached proper temperature, and just prior to processing any clinical mammograms. The test shall be an assessment of the base plus fog, mid-density, density difference, and developer temperature.

(A~~a~~) Sensitometers and densitometers used to evaluate processor performance shall be calibrated per the manufacturer's recommended calibration procedures for such devices. A record of the calibration shall be maintained until inspected by the Authority. Densitometers shall be checked against the instrument control strip at least monthly.

(B~~b~~) The mid-density and density difference action limits must be within + 0.15 of the control operating level.

(C~~c~~) The base plus fog (B+F) action limit must be within + 0.03 of the control operating level.

(D~~d~~) If the mid-density ~~and/~~or the density difference fall outside of the + 0.10 control limit but within the + 0.15 control limit for a period of three days (a trend), steps must be taken to determine the cause and correct the problem;

(E~~e~~) If the mid-density ~~and/~~or the density difference falls outside of the + 0.15 control limit, mammograms must not be processed through the processor until the cause of the problem is determined, corrected, and a repeat test is done demonstrating that the mid-density a~~nd/~~or density difference are within the + 0.15 control limit;

(F~~f~~) Processor quality control graphs must be in the format of the registrant's accrediting body or equivalent, and indicate test date/s, mid-density and density difference action limits, base plus fog action limit, film brand, type and emulsion number in use, the date when chemistry changes occurred and corrective action(s) taken when limits are exceeded;

(G~~g~~) Cross over records and calculations must be maintained until reviewed by the Authority during the annual inspection. New mid-density ~~and/~~or density difference operating levels must be charted on a new graph page.

(H~~h~~) Re-establishment of operating levels must be done in accordance with the accrediting body's protocol regarding the appropriateness of this procedure or at the specific direction of the facility's medical physicist.

(I~~i~~) While re-establishing operating levels (five day average), the facility must chart each day's results against its old operating control levels. At the end of the five days, a new chart must be established, indicating the new calculated operating limits. During the five

day average, the facility ~~will~~can not be cited for having exceeded the old processor operating levels; and

(J~~j~~) When collecting data for the five day average, a phantom image test shall be conducted each day to verify the adequacy of image quality. Should the phantom image test exceed either the 0.20 background optical density limit or the + 0.05 density difference limit, mammography must be suspended until the cause of the problem is identified and corrected, and a repeat phantom image test is shown to be within limits.

(7~~9~~) Primary/secondary barrier transmission evaluation must be conducted upon initial X-ray system installation and significant modification of the system or the facility.

(8~~10~~) Image quality. The mammography system must be capable of producing an image of the phantom demonstrating the following:~~;~~

(a) A minimum score of 4 fibers, 3 speck groups, and 3 masses (or the most current minimum score established by the accrediting body and accepted by the FDA);~~.~~

(b) Background density action limits within ± 0.20 of the control level;

(c) Density difference action limits within ± 0.05 of the control level;

(d) Milliampere seconds (mAs) within ± 15 percent of the control level;

(e) Demonstrating a level of contrast sufficient enough to clearly help define fibril, speck, and mass edges;~~.~~

(f) Without objectionable levels of image noise or quantum mottle that obscure the visualization of fibrils, specks, or masses;~~.~~

(g) Demonstrating reasonably sharp fibril, and mass margins;~~.~~

(h) With a minimum optical density (measured at the center of the phantom) of 1.20;~~.~~

(i) Phantom image test records must be in the most current format of the registrant's accrediting body or the equivalent, and indicate the exposure mode, kVp, and photo-cell used for the test as well as remarks indicating the corrective action that was taken when limits were exceeded;~~.~~

(j) When phantom image results do not meet the requirements defined in subsections (8~~10~~)(a), (b), (c), (d), (e), (f), (g), or (h) of this rule, corrective action must occur, and a repeat phantom image test must be performed demonstrating compliance, before further mammography examinations are performed using the X-ray machine.

(11) Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density difference when sensitized film is exposed to darkroom conditions with safelight on for

two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen so that after processing, an optical density of at least 1.20 is achieved.

(a) If the darkroom fog optical density difference exceeds 0.05 but is less than 0.10, mammography may be continued until the problem is corrected.

(b) If the darkroom fog optical density difference exceeds 0.10, mammography must be curtailed until the problem is corrected and the density difference no longer exceeds 0.05.

(12) Repeat rate. Corrective actions shall be recorded and the results of these corrective actions shall be assessed if the reject rate exceeds five percent or changes by two percent from the previously measured rate. The reject rate shall be based on repeated clinical images.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

333-116-0040

License Amendments

A licensee must apply for and must receive a license amendment:

(1) Before receiving or using radioactive material for a method or type of medical use not permitted by the license issued under this division;

(2) Before permitting anyone~~, except a visiting authorized user described in OAR 333-116-0110,~~ to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license except:~~. A visiting authorized user is an individual who:~~

(a) ~~Meets the requirements of OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710 or 333-116-0720, 333-116-0740 and 333-116-0760 of these rules; or~~ For an authorized user; an individual who meets the requirements in OAR 333-116-0760, 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0710 and 333-116-0720.

(b) For an authorized nuclear pharmacist; an individual who meets the requirements in OAR 333-116-0910 and 333-116-0760.~~Is a nuclear pharmacist who meets the requirements in OAR 333-116-0910 and 333-116-0760; or~~

(c) For an authorized medical physicist; an individual who meets the requirements in OAR 333-116-0905 and 333-116-0760.~~Is a medical physicist, who meets the requirements in OAR 333-116-0730, 333-116-0740, 333-116-0760 and 333-116-0905; or~~

(d) An individual ~~Is I~~identified as an authorized user, ~~or an~~ authorized nuclear pharmacist, or an authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy.~~, respectively, or~~

(3) Before changing the Radiation Safety Officer except as provided in OAR 333-116-0090;~~or Teletherapy Physicist;~~

(4) Before receiving radioactive material in excess of the amount authorized on the license;

(5) Before adding to or changing the areas of use or mailing address identified on the license; and

(6) Before revising procedures required by OAR 333-116-0495, 333-116-0580, 333-116-0583, and 333-116-0587 as applicable where such revision reduces radiation safety. ~~changing statements, representations and procedures which are incorporated into the license.~~

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0050

Notifications

(1) A licensee must provide to the Authority a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, or an authorized nuclear pharmacist~~,~~ pursuant to OAR 333-116-0040(2)(a) through (d).

(2) A licensee must notify the Authority by letter no later than 30 days after:

(a) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;~~.~~

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name does not constitute a transfer of control of the license as described in OAR 333-102-0305~~ of these rules~~; or

(d) The licensee has added to or changed the areas where radioactive material is used in accordance with OAR 333-116-0200 and 333-116-0300.

(3) The licensee must mail the documents required in this division to the Authority for review.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0090

~~Statement of~~ Authorit~~ies~~y and Responsibilities for the Radiation Protection Program

(1) In addition to the radiation protection program requirements of OAR 333-120-0020, a licensee's management must approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the Authority;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under OAR 333-116-0123.

(2) A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under OAR 333-116-0650, 333-116-0740 and 333-116-0760, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in section (7) of this rule, if the licensee takes the actions required in sections (2), (5), (7) and (8) of this rule and notifies the Authority in accordance with OAR 333-116-0050(2).

(4) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with section (3) of this rule, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(5) A licensee must establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(6) A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide corrective actions;

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(7) Licensees that are authorized for two or more different types of uses of radioactive material under ~~division 333-116~~OAR chapter 333, division 116, must establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(8) A licensee's Radiation Safety Committee must meet at intervals not to exceed six months. The licensee must maintain minutes of each meeting in accordance with OAR 333-100-0057.

(9) A licensee must retain a record of actions taken under sections (1), (2) and (5) of this rule in accordance with OAR 333-100-0057. These records must be retained for the life of the license.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Imaging and Localization

~~**333-116-0405**~~

~~**Training for Use of Sealed Sources for Diagnosis.**~~

~~Except as provided in OAR 333-116-0710, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under OAR 333-116-0400 to be a physician, dentist, or podiatrist who:~~

~~(1) Is certified by a specialty board whose certification process includes all of the requirements in sections (2) and (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or~~

~~(2) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

~~(c) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(d) Radiation biology; and~~

~~(e) Has completed training in the use of the device for the uses requested.~~

~~Stat. Auth.: ORS 453.635~~
~~Stats. Implemented: ORS 453.605 - 453.807~~

333-116-0640

Radiation Safety Officer Training and Experience Requirements

Except as provided in OAR 333-116-0740~~0650~~, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in OAR 333-116-0090 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are ~~will be~~ posted on the NRC's w~~W~~eb~~-~~page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a)(A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(B) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(C) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have two years of full-time practical training and~~/or~~ supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and~~/or~~ therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0670, ~~and~~ 333-116-0680~~;~~ or 333-116-0740;

(C) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Has completed a structured educational program consisting of 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of radioactive material; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in sections (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in paragraphs (1)(a)(A) and (1)(b)(B) or paragraphs (1)(b)(A) and (1)(b)(B) or section (2), or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0660

Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740, the licensee shall~~must~~ require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (4~~3~~) of this rule (The names of board certifications recognized by the NRC or an Agreement State are posted on the NRC's website). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670,~~,~~ 333-116-0680, ~~and 333-116-0740~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in ~~this rule,~~ OAR 333-116-0660, 333-116-0670, 333-116-0680 ~~and 333-~~

~~116-0740~~ or Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements ~~in this rule~~, in OAR 333-116-0740, 333-116-0660, 333-116-0670, ~~and~~ or 333-116-0680, ~~-~~or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0300.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0670

Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0320 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in section (4~~3~~) of this rule. (The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's website). To have its

certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in subsection (3)(a) through paragraph (2)(b)(G) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0680 and meets the requirements in OAR 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies.

(a) The training and experience must include at a ~~minimum: (a) classroom~~minimum classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or OAR 333-116-0670, 333-116-0680, 333-116-0740 and 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radiopharmaceutical drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0670(3)(b)(G), 333-116-0680, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ~~this rule or~~ OAR 333-116-0300 and 333-116-0320. ~~0680~~.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0680

Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required ~~Therapeutic Use of Radiopharmaceuticals~~

Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0360 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets ~~- includes all of~~ the requirements in ~~section~~ paragraphs (2)(b)(G) and (2)(b)(G)(ii) of this rule. (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the Nuclear Regulatory Commission's webpage). ~~and whose certification has been~~ To be recognized, a specialty board shall require all candidates for certification to: ~~by the Commission or an Agreement State; or~~

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in section (2) and subsection (2)(b). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(2)(a) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

(aA) Classroom and laboratory training in the following areas:

(Ai) Radiation physics and instrumentation;

(Bii) Radiation protection;

(Ciii) Mathematics pertaining to the use and measurement of radioactivity;

(Div) Chemistry of byproduct material for medical use; and

(Ev) Radiation biology; and

(bB) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, and sections (1) and (2) of this rule, or Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(b)(G)) as the individual requesting authorized user status. The work experience must involve:

(Ai) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(Bii) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

(C~~iii~~) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D~~iv~~) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E~~v~~) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F~~vi~~) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(G~~vii~~) Administering dosages of radiopharmaceutical drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(i~~I~~) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(ii~~II~~) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

NOTE: Experience with at least three cases in Category (vii)(2) also satisfies the requirement in Category (vii)(A).

(iii~~III~~) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; ~~and/~~or

(iv~~IV~~) Parenteral administration of any other radionuclide; and

(c~~b~~) Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~sub~~sections (1) and (2)~~(a)~~ and paragraph (2)(b)(G) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation ~~certification~~ must be signed by a preceptor authorized user who meets the requirements in ~~sections~~ OAR 333-116-0740, 333-116-0680 ~~(1), (2), of this rule~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)~~(a)~~(b~~B~~)(G~~vii~~)(i~~I~~), (ii~~II~~), (iii~~III~~), or (iv~~IV~~)) as the individual requesting authorized user status.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0683

Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission's webpage); or

(2) Is an authorized user under OAR 333-116-0680 ~~section (1) or (2)~~ for uses listed in OAR 333-116-0680(2)(b)(G)(i) or (ii) or 333-116-0687, or equivalent Agreement State requirements; or

(3)~~(a)~~ Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent Nuclear Regulatory Commission or ~~equivalent~~ Agreement State requirements. A supervising authorized user who meets the requirements in OAR 333-116-0680(2) must have experience in administering dosages as specified in OAR 333-116-0680(2)(b~~a~~)(~~B~~)(G~~vii~~)(i~~I~~) or (ii~~II~~). The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR ~~,~~333-116-0740, 333-116-0680, -333-116-0687 ~~(1) and (2), of this rule, 333-116-0687,~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in OAR 333-116-0680(2), must also have experience in administering dosages as specified in OAR 333-116-0680(2)(b~~a~~)(G~~B~~)~~(vii)(I) or~~ (ii~~II~~).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0687

Qualifications for Authorized User for Oral Administration When a Written Directive is Required

Except as provided in OAR 333-116-0740, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (3)(b) ~~(3)(c)~~ of this rule and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission webpage); or

(2) Is an authorized user under OAR 333-116-0680 ~~section~~ for uses listed in OAR 333-116-0680 ~~-~~(2)(b)(G)(ii), or equivalent Nuclear Regulatory commission or Agreement State requirements; or

(3)~~(a)~~ Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 ~~section (1) or (2)~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680. The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 ~~section (1) or (2)~~, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680(2)(a), must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii)(II).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0690

Training for Therapeutic Use of Brachytherapy Source

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using manual brachytherapy sources specified in OAR 333-116-0420 for therapy to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (2) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are posted on the NRC's webpage.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or~~

(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2)~~(a)~~ Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a~~A~~) 200 hours of classroom and laboratory training in the following areas:

(A~~i~~) Radiation physics and instrumentation;

(B~~ii~~) Radiation protection;

(C~~iii~~) Mathematics pertaining to the use and measurement of radioactivity; and

(D~~iv~~) Radiation biology; and

(b~~B)~~ 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule, OAR 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(A~~i~~) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B~~ii~~) Checking survey meters for proper operation;

(C~~iii~~) Preparing, implanting, and removing brachytherapy sources;

(D~~iv~~) Maintaining running inventories of material on hand;

(E~~v~~) Using administrative controls to prevent a medical event involving the use of byproduct material; and

(F~~vi~~) Using emergency procedures to control byproduct material; and

(c~~b~~) Has ~~obtained~~ completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in ~~this rule~~ OAR 333-116-0740, 333-116-0690, or equivalent Nuclear Regulatory Commission or -Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(d~~c~~) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ~~this rule~~ OAR 333-116-0740, 333-116-0690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a), or -subsections (2)(b~~a~~) and (2)(c~~b~~) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0700

Training for Ophthalmic Use of Strontium-90

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under OAR 333-116-0690 or equivalent Nuclear Regulatory ~~c~~Commission or Agreement State requirements; or

(2)~~(a)~~ Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose;

(D) Follow up and review of each individual's case history; and

(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, 333-116-0700~~this rule~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection~~s~~ ~~(1) and~~ (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0715

Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under OAR 333-116-~~0360~~0680 for uses listed in OAR 333-116-0680(2)(b)(G)(iii) or 333-116-0680(2)(b)(G)(iv) or equivalent Agreement State requirements; or

(2) Is an authorized user under OAR 333-116-0690 or 333-116-0720, or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in section (4) of this rule; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0690 or 333-116-0720, and who meets the requirements in section (4) of this rule.

(4)~~(a)~~ Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, ~~and/~~or parenteral administration of any other radionuclide for which a written directive is required.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740~~ or this rule,~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, ~~and/~~or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in OAR 333-116-0680 must have experience in administering dosages as specified in OAR 333-116-

0680(2)(ba)(B)(Gvii)(iii) or 333-116-0680(2)(b)(G)(iv). The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (2) or (3) subsections (4)(b) or (4)(c) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or this rule, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680, must have experience in administering dosages as specified in OAR 333-116-0680(2)(ba)(GB)(vii)(iii) or 333-116-0680(2)(b)(G)(iv).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0720

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in OAR 333-116-0740, the licensee must require the authorized user of a sealed source specified in OAR 333-116-0480 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission (NRC) or an Agreement State and who meets the requirements in subsection (2)(c) and section (3) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are~~will be~~ posted on the NRC's web-page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2)~~(a)~~ Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit~~ that includes~~:

(a) Which includes the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740~~this rule~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

(iii) Using administrative controls to prevent a medical event involving the use of byproduct material;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740~~this rule~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) or (2)(a) and (2)(b), and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 ~~this rule~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0740

Training for Experienced Authorized User, Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Nuclear Pharmacist or Authorized Nuclear Pharmacist

(1) An individual identified as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and

authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 ~~who perform only those methods of use for which they were authorized on that date~~ need not comply with the training requirements of OAR 333-116-0640, ~~through 333-116-0760 and~~ 333-116-0905 ~~through~~ or 333-116-0910~~5~~.

(2) Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Authority, Nuclear Regulatory Commission or Agreement State or Licensing State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements ~~of~~ OAR 333-116-0640, 333-116-0905, or 333-116-0910. ~~through 333-116-0760~~.

(3) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Specific Requirements for Positron Emission Tomography (PET) Facilities

333-116-0880

Training and Experience for PET, PET/CT and SPECT/CT Personnel

(1) Pharmacy or chemistry personnel must have 40 extra hours above Nuclear Pharmacy requirements and 40 hours specific to PET. The 40 hours can~~should~~ be divided equally between didactic and practical applications.

(2) Authorized users who meet training requirements for human use in OAR 333-116-0670 must complete an additional 40 hours at an accepted PET training center.

(3) Technical personnel working under an authorized user must have basic radiation safety training, plus 40 additional hours specific to PET.

(4) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems must be operated by technologists licensed by the Oregon Board of Medical Imaging who are:

(a) Any registered radiographer with the credential R.T. (R); ~~or~~

(b) Registered radiation therapist with the credential R.T. (T); ~~and~~

(~~c) Who are currently licensed by the Oregon Board of Radiologic Technology; or~~

(c~~d~~) Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(d~~e~~) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(5) The individuals mentioned in section (4) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

(6)(a) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority; and

(b) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or

(c) Individuals meeting the requirements of section (4) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (6)(a) of this rule.

(7) An R.T. (N) or CNMT certified in Computed Tomography through the American Registry of Radiologic Technologists is considered to have met the training requirements in section (4) of this rule.

(8) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0905

Training for Authorized Medical Physicist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection

(2)(b) and section (3) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and~~/or~~ supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740~~, 333-116-0720~~, 333-116-0690 or ~~,~~ 333-116-0720 ~~or 333-116-0740~~; and

(c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2)~~(a)~~ Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(a) This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

(C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(D) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) and (1)(b) ~~and section (3)~~ of this rule, or subsection (2)(a) and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, OAR 333-116-0740, 333-116-0905,~~10 CFR part 35~~ or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 118

TRANSPORTATION OF RADIOACTIVE MATERIAL

Operating Controls and Procedures

333-118-0150

Routine Determinations

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this division and of the license. The licensee shall determine that:

(1) The package is proper for the contents to be shipped.

(2) The package is in unimpaired physical condition except superficial defects such as marks or dents.

(3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects.

(4) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid.

(5) Any pressure relief device is operable and set in accordance with written procedures.

(6) The package has been loaded and closed in accordance with written procedures.

(7) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45.

(8) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition.

(9) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in Department of Transportation regulations outlined in 49 CFR Part 173.443.

(a) External radiation levels around the package and around the vehicle, if applicable, can~~will~~ not exceed the limits specified in 10 CFR Part 71.47 at anytime during transportation; and

(b) Accessible package surface temperatures can~~will~~ not exceed the limits specified in 10 CFR Part 71.43(g) at any time during transportation.

(10) External radiation levels around the package and around the vehicle, if applicable, cannot exceed the limit specified in 10 CFR Part 71.45 at any time during transport.

(11) Accessible package surfaces temperatures cannot exceed the limits specified in 10 CFR Part 71.43.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 119

REGISTRATION OF TANNING FACILITIES

General Requirements

333-119-0040

Construction and Operation of Tanning Facilities

Unless otherwise ordered or approved by the Authority, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

~~(1) Physical facilities:~~

(1~~a~~) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a water closet and hand washing sinks. Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

(2~~b~~) All areas of the tanning facility shall be ventilated with at least six air changes per hour or as required by local code.

(3~~c~~) Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during booth operation.

(4~~d~~) The tanning device shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).

(5~~e~~) Except as otherwise noted by the Authority, each tanning facility shall be constructed, operated and maintained in accordance with applicable city, county and state codes.

(6) Clean sanitary towels shall be provided to all patrons using tanning facilities.

(7) A hamper or receptacle must be provided for all soiled towels and linen.

(8) No pets or animals are permitted in tanning facilities other than service animals.

~~(2) Cleaning and maintenance:~~

~~(a) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator in accordance with manufacturer's instructions.~~

~~(b) The tanning device(s) and protective eyewear shall be cleaned with an approved sanitizer after each use by the facility operator. A listing of approved sanitizers is maintained by the Authority and is available upon request of registrants. This listing may change at any time due to updating of state or federal sanitation guidelines. The operator shall use a sanitizer that sanitizes to a safe level of microorganisms as required by these rules. A clean paper or cloth towel shall be used each time the tanning device is cleaned and sanitized. The sanitizer, as described in these rules, is one specifically manufactured for sanitizing ultraviolet light emitting equipment and protective eyewear, and that does not damage the acrylic lamp covers of the device. The Ultraviolet Light produced by the tanning device itself is not considered an adequate sanitizing agent.~~

~~(c) Protective eyewear and tanning devices shall be sanitized after each use with a sanitizing agent that is registered by EPA and approved by the Authority using the following procedures:~~

~~(A) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with a solution) containing at least 400 ppm (parts per million) of available quaternary ammonium compound at a temperature of at least 75 degrees Fahrenheit; or~~

~~(B) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with the solution) containing at least 100 ppm (parts per million) of available chlorine as a hypochlorite and at a temperature of at least 75 degrees Fahrenheit.~~

~~(d) A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and at least weekly thereafter to ensure sufficient strength of the sanitizing solution. If a suitable test kit is not available for an approved sanitizer, the laboratory analysis data shall be provided by the product manufacturer, and a copy of it be on file with the Authority. Written procedures at the facility using sanitizer shall include proper mixing and handling instructions to assure proper concentration of the sanitizer.~~

~~(e) Clean sanitary towels shall be provided to all patrons using tanning facilities.~~

~~(f) A hamper or receptacle must be provided for all soiled towels and linen.~~

~~(g) No pets or animals are permitted in tanning facilities other than service animals.~~

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930

333-119-0041

Cleaning and Sanitation

(1) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator.

(2) The tanning device(s) and protective eyewear shall be cleaned after each use by the facility operator in accordance with the manufacturer's instructions.

(3) A clean paper or cloth towel shall be used each time the tanning device is cleaned and sanitized.

(4) The sanitizer must be specifically manufactured for sanitizing ultraviolet light emitting equipment and protective eyewear, and must not damage the acrylic lamp covers of the device. The ultraviolet light produced by the tanning device itself is not considered an adequate sanitizing agent.

(5) An operator cannot require the consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer.

(6) The sanitizer must contain a concentration of Quaternary Ammonium between 400ppm-800ppm. A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and tested weekly thereafter to ensure sufficient strength remains within the sanitizing solution.

(7) A written policy for cleaning and sanitizing shall be available for employees and the consumer. Written policies need to address the following:

(a) Tanning device manufacturer's recommended sanitizer solution and cleaning guidelines. If the manufacturer does not recommend a specific sanitizer then the written policy shall contain the name of the sanitizer that is being used on the tanning device and eyewear.

(b) Materials Safety Data Sheets referring to the sanitizing agent used by the operator.

(c) Location of the sanitizer and the application instructions.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

Specific Requirements

333-119-0080

Training of Personnel

(1) The registrant shall maintain documentation to verify that all tanning device operators are adequately trained in the following:

(a) The rules of this division;

(b) Procedures for correct operation of the tanning facility and tanning devices;

(c) Recognition of injury or overexposure to Ultraviolet radiation;

(d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices;

(e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices;

(f) Emergency procedures to be followed in case of injury; and

(g) Potential photosensitizing foods, cosmetics, and medications.

(2) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.

(3) ~~On or after July 1, 2011,~~ A~~a~~ll operators of registered tanning devices must successfully complete an Authority approved tanning training course in the State of Oregon prior to commencement of tanning operations.

~~(4) Prior to July 1, 2011:~~

~~(a) At least one owner, manager, or operator from each tanning facility with four or less tanning devices, shall successfully complete one of the vendor-provided formal training courses authorized by the Authority.~~

~~(b) At least two operators from each tanning facility with five or more tanning devices shall successfully complete one of the vendor provided formal training courses authorized by the Authority.~~

~~(c) Training of other full or part-time operators shall be by means of a Authority-authorized and vendor-provided training course, or by materials received by an owner or primary operator from a Authority-authorized and vendor-provided training course, or by a Authority-authorized correspondence course.~~

~~(5) Staff training shall be documented by the facility owner or operator and include copies of training certificates.~~

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

Records

333-120-0630

Determination of Prior Occupational Dose

(1) For each individual likely to receive, in a year, an occupational dose requiring monitoring pursuant to OAR 333-120-0210, the licensee or registrant must:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant must determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(3) In complying with the requirements of section (1) or (2) of this rule, a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year; or

(b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date NRC~~Authority~~ Form 4~~Y~~, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant); and

(c) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant must request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant must record the exposure history, as required by section (1) of this rule, on NRC Form 4~~Authority Form Y~~, or other clear and legible record, of all the information required on NRC Form 4~~Y~~. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant must use the

dose shown in the report in preparing NRCAuthority Form 4Y. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant must place a notation on Authority Form Y NRC Form 4 indicating the periods of time for which data are not available.

NOTE: Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed under OAR 333-104 (repealed 1994). Further, occupational exposure histories obtained and recorded on Authority Form Y before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant must assume:

(a) In establishing administrative controls under OAR 333-120-0100(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant must retain the records on NRCAuthority Form 4Y or equivalent until the Authority terminates each pertinent license or registration requiring this record. The licensee or registrant must retain records used in preparing NRCAuthority Form 4Y in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Reports

333-120-0730

Reports of Planned Special Exposures and Individual Monitoring

(1) The licensee must submit a written report to the Authority within 30 days following any planned special exposure conducted in accordance with OAR 333-120-0150 informing the Authority that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by OAR 333-120-0640.

(2) The following licensees must have available for inspection by the Authority submit a written report to the Authority on or before April 30 of each year, documenting results of

individual monitoring carried out by the licensee for each individual for whom monitoring was required pursuant to OAR 333-120-0210 during that year.

(a) Licensees authorized to possess or use radioactive material for purposes of radiography pursuant to division 102 and 105 of these rules; or

(b) Licensees who receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61; or

(c) Licensees who possess or use at any time, for processing or manufacturing for distribution pursuant to division 102 or 116 of these rules, radioactive material in quantities exceeding any one of the following quantities:

Quantity of Radionuclide in Curies:

(A) Cesium-137 — 1;

(B) Cobalt-60 — 1;

(C) Gold-198 — 100;

(D) Iodine-131 — 1;

(E) Iridium-192 — 10;

(F) Krypton-85 — 1,000;

(G) Promethium-147 — 10;

(H) Technetium-99m — 1,000.

The Authority may require as a license condition, or by rule, regulation, or order pursuant to OAR 333-100-0030, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

NOTE: The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use NRC's Form 5 or electronic media containing all the information required by NRC's Form 5.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

DIVISION 123

THERAPEUTIC RADIATION MACHINES

333-123-0005

Definitions

(1) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of DE by DM, where DE is the mean energy imparted by ionizing radiation to matter of mass DM. The SI unit of absorbed dose is joule/kg and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(2) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(4) "Added filtration" means any filtration which is in addition to the inherent filtration that is in the primary beam.

(5) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of DE/DM, where DE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass DM. The SI unit of air kerma is joule/kg.

(6) "Barrier" has the same meaning as ~~See~~ protective barrier".

(7) "Beam axis" means the axis of rotation of the beam-limiting device.

(8) "Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(9) "Beam monitoring system" means the system designed and installed in the radiation head to detect and appropriately measure the radiation present in the useful radiation beam.

(10) "Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(11) "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(12) "Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

(13) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than 5 cm.

(14) "Conventional Simulator" means any ~~x-ray~~X-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

(15) "CT Simulator" means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine, and that allows import, manipulation, display and storage of images from CT and~~/or~~ other imaging modalities.

(16) "Detector" has the same meaning as ~~See~~ ~~"~~radiation detector".

(17) "Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(18) ~~"~~Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(19) ~~"~~Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the X-ray tube, the control mechanism, the cooling system, and the power source.

(20) ~~"~~Electronic brachytherapy source" means the X-ray tube component used in an electronic brachytherapy device.

(21~~18~~) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a specified distance from the body.

(22~~19~~) "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

(23~~20~~) "Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to OAR 333-123-0025(2) and (3).

(24~~21~~) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(25~~22~~) "Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule/kg. The previous unit of absorbed dose (rad) is being replaced by the gray. (1 Gy = 100 rad; 1 cGy = 1 rad).

(26~~23~~) "Half-value layer (HVL)" means the thickness of a specified material which attenuates incident ionizing radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(27~~24~~) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities, which have been determined by various computer-based optimization techniques.

(28~~25~~) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(29~~26~~) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(30~~27~~) "Irradiation" means the exposure of a living tissue or matter to ionizing radiation.

(31~~28~~) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry, collimator and couch move through the full range of motions.

(32~~29~~) "Kilovolt (kV) (kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

Note: C~~c~~urrent convention is to use kV for photons and keV for electrons.

(33~~30~~) "Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

(34~~31~~) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(35~~32~~) "Light field" means the area illuminated by light, simulating the radiation field.

(36~~33~~) "mA" means milliamperes.

(37~~34~~) "Medical Treatment Event" means an event that meets the criteria in 333-123-0020(1).

(38~~35~~) "Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

Note: C~~c~~urrent convention is to use MV for photons and MeV for electrons.

(39~~36~~) "Monitor unit (MU)" has the same meaning as~~See~~ ~~-d~~ose monitor unit".

(40~~37~~) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes, but is not limited to arc, conformal, intensity modulation and rotational therapy.

(41~~38~~) "Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit port of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For ~~x-ray~~X-ray irradiation, the distance from the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance must be that specified by the manufacturer.

(42~~39~~) "Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

(43~~40~~) "Peak tube potential" means the maximum value of the potential difference across the ~~x-ray~~X-ray tube during an exposure.

(44~~41~~) "Periodic quality assurance check" means a procedure, which is performed at regular intervals to ensure that previously determined machine characteristics continue to be valid.

(45~~42~~) "Phantom" means an object responding in essentially the same manner as tissue, with respect to absorption or scattering of the incident ionizing radiation in question.

(46~~43~~) "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from Bremsstrahlung ~~x-ray~~X-rays.

(47~~44~~) "Prescribed dose" means the total dose and dose per fraction as documented in the physician's written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

(48~~45~~) "Primary dose monitoring system" means a system which can~~will~~ monitor the useful beam during irradiation and which can~~will~~ terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(49~~46~~) "Primary protective barrier" has the meaning given that term in section (50) of this rule. ~~See~~ protective barrier".

(50~~47~~) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) Primary protective barrier means the material, excluding filters, placed in the useful beam.

(b) Secondary protective barrier means the material, which attenuates stray radiation.

(51~~48~~) "Qualified Expert" means an individual qualified in accordance with OAR 333-100-0005.

(52~~49~~) "Qualified Medical Physicist" means an individual qualified in accordance with OAR 333-123-0015(2)(b).

(53~~50~~) "Qualified Radiation Therapy Physician" means an individual qualified in accordance with OAR 333-123-0015(1).

(54~~51~~) "Radiation detector" means a device, which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(55~~52~~) "Radiation field" has the same meaning as~~See~~ ~~u~~useful beam".

(56~~53~~) "Radiation head" means the structure from which the useful beam emerges.

(57~~54~~) "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(58~~55~~) "Scattered primary radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(59~~56~~) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

(60~~57~~) "Secondary dose monitoring system" means a system, which will terminate irradiation in the event of failure of the primary dose monitoring system.

(61~~58~~) "Secondary protective barrier" has the meaning given that term in section (50) of this rule, ~~See~~ ~~p~~rotective barrier".

(62~~59~~) "Service Engineer" means an individual who is qualified to service the radiation therapy equipment per manufacturer's standards.

(63~~60~~) "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

(64~~61~~) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(65~~62~~) "Sievert (Sv)" means the SI unit of dose equivalence. The unit of dose equivalence is the joule/kg. The previous unit of dose equivalence (rem) is being replaced by the Sievert. [1 Sv=100 rem].

(66~~63~~) "Simulator (radiation therapy simulation system)" means any ~~x-ray~~X-ray system intended for localizing the tissue volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. See Conventional Simulator and Virtual Simulator.

(67~~64~~) "Source" means the focal point ~~and/~~or material from which the radiation emanates.

(68~~65~~) "Source-skin distance (SSD)" has the same meaning as ~~See~~ ~~t~~target-skin distance".

(69~~66~~) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(70~~67~~) "Stray radiation" means the sum of leakage and scattered radiation.

(71~~68~~) "Target" means that part of an ~~x-ray~~X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(72~~69~~) "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the ~~x-ray~~X-ray target ~~and/~~or electron virtual source to the surface of the irradiated object or patient.

(73~~70~~) "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(74~~71~~) "Termination of irradiation" means the stopping of irradiation in a fashion, which can~~will~~ not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(75~~72~~) "Therapeutic radiation machine" is a complex system designed and used for external beam radiation therapy. This system includes some or all of the following: equipment producing ionizing radiation (including, but not limited to ~~x-ray~~X-rays, electrons, protons and neutrons), beam shaping devices, computer control unit, verify and record system, electronic portal imaging, treatment planning computer and other ancillary systems.

(76~~73~~) "Tube" means an ~~x-ray~~X-ray tube, unless otherwise specified.

(77~~74~~) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and~~/or~~ filament transformers and other appropriate elements when such are contained within the tube housing.

(78~~75~~) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

(79~~76~~) "Virtual source" means a point from which radiation appears to originate.

(80~~77~~) "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the useful beam.

(81~~78~~) "Written directive" means an order, written or electronic, for the administration of radiation to a specific patient as specified in OAR 333-123-0045(2).

(82~~79~~) "X-ray tube" means any electron tube, which is designed to be used primarily for the production of ~~x-ray~~X-rays.

Stat. Auth: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0055

Electronic Brachytherapy

(1) Electronic brachytherapy devices shall be exempt from the requirements in OAR 333-123-0025.

(a) An electronic brachytherapy device that does not meet the requirements of this rule shall not be used for irradiation of patients; and

(b) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the Authority.

(2) Each facility location authorized to use an electronic brachytherapy device shall possess calibrated portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with OAR 333-123-0010 for the applicable electronic brachytherapy source energy.
Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-123-0060

Facility Design Requirements for Electronic Brachytherapy Devices

(1) In addition to shielding adequate to meet the requirements of division 120 of this chapter, a treatment room where an electronic brachytherapy device is used shall:

(a) Prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room if applicable;

(b) Have a door at any entrance; and

(c) Permit communication with and visual observation of the patient from the treatment control panel during the irradiation from an electronic brachytherapy device.

(2) For electronic brachytherapy devices capable of operating at or below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

(3) For electronic brachytherapy devices capable of operating at greater than 150 kV:~~-~~

(a) The control panel shall be located outside the treatment room; and

(b) Electrical interlocks shall be provided for all doors providing entrance into the treatment room that can:

(A) Prevent the operator from initiating the treatment cycle if a door remains open;

(B) Cause the source to be shielded when an entrance door is opened; and

(C) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0065

Electrical Safety for Electronic Brachytherapy Devices

(1) A high voltage transformer shall:

(a) Be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment;

(b) Be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open; and

(c) Have appropriate safety labels warning personnel of potential electrical shock and heat related injuries.

(24) Brachytherapy manufactured equipment shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) documents:

(a) IEC 60601-1:1998+A1+A2:1995;

(b) IEC 60601-1-2:2001;

(c) IEC 60601-2-8:1999; and

(d) IEC 60601-2-17:2004.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0070

Control Panel Functions

A control panel must be designed to provide:

(1) An indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(2) An indication of whether X-rays are being produced;

(3) A means for displaying electronic brachytherapy source accelerating voltage(kV), beam current(µA), pre-set value of radiation dose(cGy) and real time display of dose delivered;

(4) The means for terminating an exposure at any time; and

(5) An access locking control device that can prevent unauthorized use of the electronic brachytherapy device.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0075
Timer

An irradiation control device timer shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

(1) A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining;

(2) A timer shall not permit an exposure if set at zero;

(3) A timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(4) A timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation;

(5) A timer shall permit setting of exposure times as short as 0.1 second;

(6) A timer shall be accurate to within one percent of the selected value or 0.1 second, whichever is greater; and

(7) A redundant treatment monitoring system (backup timer) shall be present at the treatment console to use as the treatment stop criterion in case the primary treatment control device timer malfunctions.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0080

Medical Physicist

A Qualified Medical Physicist who meets the requirements of OAR 333-123-0015 is required in facilities having electronic brachytherapy devices. A Medical Physicist is responsible for:

(1) Evaluation of the output from the electronic brachytherapy source;

(2) Generation of the necessary dosimetric information;

(3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in sections (1) through (6) of this rule and OAR 333-123-0100;

(5) Consultation with a Radiation Therapy Physician in treatment planning as needed; and

(6) Performing calculations and assessments regarding patient treatments that may constitute a misadministration.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0085

Operating Procedures

(1) Only individuals approved by a Radiation Therapy Physician, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment.

(2) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of OAR 333-123-0010(4), 333-123-0090 and 333-123-0095 have been met.

(3) The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel.

(4) During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(6) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

(b) The names and telephone numbers of the Radiation Therapy Physician, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(7) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. For control consoles that are integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.

(8) Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(9) A Radiation Therapy Physician shall be notified as soon as possible if the patient receiving brachytherapy treatment has a medical emergency, suffers injury or dies. A Radiation Safety Officer or designee shall be notified as soon as possible if there is any radiation related injury to the patient. A Radiation Safety Officer or a Qualified Medical Physicist shall inform the manufacturer and the Authority of the event.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0090

Safety Precautions for Electronic Brachytherapy Devices

(1) A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized.

(2) A Radiation Therapy Physician and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.

(3) A Qualified Medical Physicist and either an authorized user or a Radiation Therapy Physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device.

(4) When shielding is required by OAR 333-123-0060, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of division 120 of this chapter for any individual, other than the patient, in the treatment room.

(5) All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0095

Electronic Brachytherapy Source Calibration Measurements

(1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of a Qualified Medical Physicist.

(2) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source annually, or after any repair affecting the X-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks.

(3) Calibration of the electronic brachytherapy source output shall utilize a calibration procedure in accordance with OAR 333-123--0010(5). The dosimetry system shall have been calibrated at the applicable electronic brachytherapy source energy.

(4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

(a) The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;

(b) Timer accuracy and linearity over the typical range of use;

(c) Proper operation of back-up exposure control devices;

(d) Evaluation that relative dose distribution around the source is within the limit recommended by the manufacturer or recommendations from a recognized national professional association in electronic brachytherapy (when available); and

(e) Source positioning accuracy to within 1 mm within the applicator.

(5) Calibration of the X-ray source output shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

(6) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include:
(a) The date of the calibration;
(b) The manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;
(c) The model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and
(d) The name and signature of the Qualified Medical Physicist responsible for performing the calibration.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0100

Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

(1) Quality assurance checks shall be performed by the medical physicists on each electronic brachytherapy device subject to this rule.

(a) At the beginning of each day of use; and

(b) After each X-ray tube installation.

(2) The registrant shall perform periodic quality assurance checks required by this rule in accordance with procedures established by -a Qualified Medical Physicist.

(3) To satisfy the requirements of this rule, radiation output quality assurance checks shall include at a minimum:

(a) Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:

(A) Output as a function of time; or

(B) Output as a function of setting on a monitor chamber.

(b) Verification of the consistency of the dose distribution to the output within two to three percent of the expected value, if applicable, or determination of the output if there is no expected value of that found during calibration required by OAR 333-123-0095.

(c) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm.

(4) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in OAR 333-123-0010(5) to make the quality assurance checks required in this rule.

(5) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(a) A Radiation Therapy Physician and a Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use

until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances.

(b) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either a Radiation Therapy Physician or Qualified Medical Physicist within two days.

(c) A Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

(6) To satisfy the requirements of this rule, safety device quality assurance checks shall, at a minimum, assure:

(a) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

(b) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(c) Proper operation of radiation monitors, if applicable;

(d) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(e) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(7) If the results of the safety device quality assurance checks required in this rule indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

(8) A registrant shall maintain a record of each quality assurance check required by sections (3) and (7) of this rule in an auditable form for three years.

(a) The record shall include:
(A) The date of the quality assurance check;
(B) The manufacturer's name, model number and serial number for the electronic brachytherapy device;
(C) The name and signature of the individual who performed the periodic quality assurance check; and
(D) The name and signature of the Qualified Medical Physicist who reviewed the quality assurance check.

(b) For radiation output quality assurance checks required by this rule, the record shall also include the unique identifier for the electronic brachytherapy source and the

manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.
Stat. Auth: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0105

Therapy Related Computer Systems

(1) A registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

(a) Acceptance testing shall be performed by, or under the direct supervision of a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radiation source positions from radiographic images, if applicable; and

(E) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfers of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(2) The position indicators in the applicator shall be compared to the actual position of the source or planned swell positions, as appropriate, at the time of commissioning.

(3) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by a Radiation Therapy Physician and a Qualified Medical Physicist for correctness through means independent of that used for determination of the parameters.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0110

Training

(1) A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in OAR 333-123-0085. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

(2) In addition to the requirements of OAR 333-123-0015(1) for Radiation Therapy Physicians and OAR 333-123-0015(2) for Qualified Medical Physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

(a) Device-specific radiation safety requirements;
(b) Device operations;

(c) Clinical use for the types of use approved by the FDA;

(d) Emergency procedures, including an emergency drill; and

(e) The registrant's Quality Assurance Program.

(3) A registrant shall retain a record of individuals receiving instruction required by this rule for three years. The record shall include:
(a) A list of the topics covered;~~.~~
(b) The date of the instruction;~~.~~
(c) The name(s) of the attendee(s);~~.~~ and
(d) The name(s) of the individual(s) who provided the instruction.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-123-0115

Mobile Electronic Brachytherapy Service

A registrant providing mobile electronic brachtherapy service shall, at a minimum:

(1) Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;

(2) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address; and

(3) Perform, at each location on each day of use, all of the required quality assurance checks specified in OAR 333-123-0100 to assure proper operation of the device.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

NEWSLETTERS & ARTICLES OF INTEREST

Nothing to report under this tab

LICENSE RATIFICATION

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16 . RATIFICATION OF LICENSES

As authorized by the Board, licenses to practice dentistry and dental hygiene were issued to applicants who fulfilled all routine licensure requirements. It is recommended the Board ratify issuance of the following licenses. Complete application files will be available for review during the Board meeting.

Dental Hygiene

H6368	KRISTINE REE CALLAGHAN, R.D.H.	9/26/2012
H6369	LYNN M MANLEY, R.D.H.	10/2/2012
H6370	DONNA L HAMILTON, R.D.H.	10/2/2012
H6371	CASSANDRA J BUTTON, R.D.H.	10/2/2012
H6372	CHALENE D CARSON, R.D.H.	10/2/2012
H6373	CHEYENNE N BURNETT, R.D.H.	10/2/2012
H6374	KATIE L FAULKNER, R.D.H.	10/2/2012
H6375	ROSA HERRERA, R.D.H.	10/9/2012
H6376	KATHLEEN S RUSSELL, R.D.H.	10/9/2012
H6377	TRACY CAMPOS, R.D.H.	10/9/2012
H6378	CLAUDIA Y CARRILLO, R.D.H.	10/9/2012
H6379	JENNIFER M BLATTER, R.D.H.	10/9/2012
H6380	JESSICA H MATEO-DE-ACOSTA, R.D.H.	10/9/2012
H6381	AMANDA A GRAY, R.D.H.	10/10/2012
H6382	LYNDELL H WINTERS, R.D.H.	10/10/2012
H6383	HENRIETTA E MARTIN, R.D.H.	10/10/2012
H6384	PATRICIA K GOLDMAN, R.D.H.	10/10/2012
H6385	TERESA L MONGER, R.D.H.	10/15/2012
H6386	EUN JEONG ASBURY, R.D.H.	10/15/2012
H6387	HILLARY D GARNER, R.D.H.	10/15/2012
H6388	SARAH A LARRABEE, R.D.H.	10/23/2012
H6389	KIMBERLY R COOK, R.D.H.	10/23/2012
H6390	TRACY A MONTMENY, R.D.H.	10/23/2012
H6391	ELAINE M PETRO, R.D.H.	10/23/2012
H6392	SAVANNAH H ROSE, R.D.H.	10/26/2012
H6393	ERICA R HOCHHALTER, R.D.H.	10/26/2012
H6394	KELSEY M ALTRINGER, R.D.H.	10/26/2012
H6395	TAREN KATRINA LARSEN, R.D.H.	10/26/2012
H6396	GENEVIEVE E WARNER, R.D.H.	10/26/2012
H6397	KANDICE A JOHNS, R.D.H.	10/31/2012
H6398	DEBRA L GRUZENSKY, R.D.H.	10/31/2012
H6399	CAROL B LINCER, R.D.H.	10/31/2012
H6400	ASHLEY E JACOBS, R.D.H.	11/1/2012
H6401	ROXANE J TUNTLAND, R.D.H.	11/1/2012
H6402	MELISSA E RICH, R.D.H.	11/8/2012
H6403	MOSTAFA ALAOUI, R.D.H.	11/9/2012
H6404	DANEY SPRIET, R.D.H.	11/13/2012
H6405	KAYLEIGH A TROMBLY, R.D.H.	11/19/2012
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H6404	DANEY SPRIET, R.D.H.	11/13/2012
H6405	KAYLEIGH A TROMBLY, R.D.H.	11/19/2012
H6406	SHANDA M BARRETT, R.D.H.	11/19/2012
H6407	JULIE M FLAGER, R.D.H.	11/19/2012
H6408	AMY L LUND, R.D.H.	11/27/2012
H6409	TRUDY ADELINE HOGG, R.D.H.	11/27/2012
H6410	DANIELLE M HOLT, R.D.H.	11/29/2012

Dentists

D9795	BRADLEY S MORTENSON, D.M.D.	10/2/2012
D9796	CHRISTOPHER W KYLES, D.M.D.	10/2/2012
D9797	WILLIAM B FUGERE, D.M.D.	10/2/2012
D9798	JAMES A BELL, D.M.D.	10/2/2012
D9799	CHRISTIAN B KECHT, D.D.S.	10/2/2012
D9801	DANIEL J POELMAN, D.D.S.	10/9/2012
D9802	PAUL PANTLEO, D.D.S.	10/9/2012
D9803	TAEYOUNG KIM, D.D.S.	10/15/2012
D9804	JEAN A LEWIS, D.M.D.	10/23/2012
D9805	ADAM P CRAMER, D.D.S.	10/23/2012
D9806	ALEXANDER K JHANG, D.D.S.	10/23/2012
D9807	JUSTIN HOLLAR, D.M.D.	10/26/2012
D9808	SCOTT J ANDREWS, D.M.D.	10/26/2012
D9809	HOLLY A THOMPSON, D.D.S.	10/26/2012
D9810	MATTHEW E LESH, D.M.D.	10/31/2012
D9811	MICHAEL C HAYMORE, D.D.S.	10/31/2012
D9812	JAMES D DINGER, D.M.D.	11/7/2012

D9813	ALEXIS R COSTON, D.D.S.	11/7/2012
D9814	STEVEN A NELSON, D.D.S.	11/8/2012
D9815	SHIRLEY G CHEUNG, D.M.D.	11/8/2012
D9816	KAUSHALI PATEL, D.M.D.	11/9/2012
D9817	JORDAN M BINIKER, D.D.S.	11/13/2012
D9818	BRETT B HULET, D.D.S.	11/19/2012
D9819	MELISA T SUSANTO, D.D.S.	11/29/2012
D9820	MONI AHMADIAN, D.M.D.	11/29/2012
DF0026	MANOEL ROBERTO MACEDO,	10/9/2012

Pediatric Dentistry

D9800	PATRICIA A PEIRANO FRANKLIN,	10/9/2012

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