

**Summary of Submissions and Responses - National Directory for Radiation Protection –
Draft Amendment No. 4 - Solaria
Submissions closing date: 14 November 2008**

SUBMITTER	COMMENT	RESPONSE
<p>01 Mark Konemann Amber leisure Australia Pty Ltd</p>	<p>THE REGULATORY IMPACT STATEMENT ON THE SOLARIUM INDUSTRY.</p> <p>MOST of the figures are only estimates and suggestions that only refer to govt. department studies mainly, I cannot see mention of studies or reports showing 'no association of solarium and melanoma', as there are also many.</p> <p>In relation to the solarium industry, the figures are quoted at the peak of the industry 2006/2007 and now (2008) with more than 50% of salons closed over the last 12 months and in view of the current economic climate, these figures and studies are now much outdated and should be completely reviewed to make a more accurate assessment of the current industry and business climate.</p> <p>You may have already seen the false claims by media and cancer groups in regards to the solarium industry being 5 times the power of the sun, and as APRPANSAs tests now show these claims are were false and the solarium industry was made the victim again for what I believe to be more funding opportunities.</p> <p>Estimates are only that ,estimates, we need raw facts not estimates when considering regulation that clearly impacts small business and sectors such as unemployment and the flow on effect by business not having disposable funds to expend .</p> <p>The 'Gordon' report states that solarium industry markets health benefits, but in my 20 years of service I have not seen this to be prevalent.</p> <p>The report also states that only 50% of solarium were compliant in regards to 16-17 year olds ,this is again false as the guidelines are again just that 'guides' at the time of this report. The 'Gordon' report is in my opinion sensational and one sided.</p>	<p>The most relevant recent studies have been used.</p> <p>The figures used were the most recently available.</p> <p>The Australian Standard does allow solarium lamps to be up to 5 times more powerful than the sun.</p> <p>The information used should be as reliable as possible.</p> <p>Disagreed</p> <p>Disagreed</p>

<p>If the lag period for melanoma is 10 years why then why have I seen no cases of skin cancer let alone melanoma in 20 years of my service?</p> <p>Amazingly though since introduction of anti sun campaigns and sunscreen the rate of cancer mainly breast cancer in Australia has been said to have more than tripled.</p> <p>The impact statement says that the economic losses will transfer to other services offered by the solarium industry, this is False, not every salon will have the funds to buy new or offer new services, when a clients leaves a salon for a particular reason the whole salon suffers and as client retention fails, if a client is patronizing a salon for 1 reason there is no evidence that if this service is stopped that the clients attend the salon now for other services for 'that dollar spend'. This is a known fact and absurd to even suggest, if that was the case, the large number of salons now closed would still be open. Solarium clients are not Spray tan clients.</p> <p>In the summary it is noted that the industry is not restricted, this is debatable as 16-17 YEAR OLDs are restricted to use the solarium with parental consents , without this choice, clearly now forces more kids to the beach for uncontrolled tanning practices.</p> <p>The impact statement predicts solarium would lose 19% of the income thru skin types one not tanning, although I feel skin types 1, do not require tanning by choice typically , but taking the industry into consideration what compensation is available for the industry for business that may already have skin type 1 on prepaid sessions? Small business cannot be expected to refund 19 % of clients in the current economic climate.</p> <p>One can also clearly see that the cost of monitoring compliance of salons is not enough, also now because this figure can now be halved as over half the salons have now closed and further closures are predicted in the impact statement once regulations are imposed.</p> <p>What steps will be taken to educate small business in regards to new regulations.</p> <p>In the <i>Confounding Behaviour</i> section it states that' At the same time, they are likely to be offered alternatives such as a "spray tan" that do not entail the same risks" yes this is true but there are no mention on the risks spray tans</p>	<p>More than likely by the time a skin cancer or melanoma has developed the client is no longer a solarium customer</p> <p>Sunsmart campaigns relate to skin cancers</p> <p>Disagreed</p> <p>Sunsmart messages are designed to address this possibility</p> <p>Outside the scope of this RIS.</p> <p>Cost of monitoring compliance is affected by the individual approaches to enforcement taken by regulators in each jurisdiction and can only be estimated here.</p> <p>A matter for individual jurisdictions when regulation is introduced.</p> <p>There is little published information available.</p>
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	<p>have , or the costs involved to government in regards to already noted skin rashes , allergies, overheating, fainting ,fits and general feeling of sickness after some spray tans. Also the predicated effect of the chemicals that are applied to the skin on continuous use of the dye being applied to membranes.</p> <p>One the 'NCPA' there may be restrictive trade in regards to lamp suppliers not being able to offer certain lamps as some now must comply with 0.9 med maximum outputs.</p>	<p>This has been included in the Australian Standard for some years already and manufacturers should already comply.</p>
<p>02 Sam Zouzounis Senior Program Officer Radiation Safety Section Environmental Health Unit Public Health Branch Department of Human Services, VIC</p>	<p><u>Comments from the Department of Human Services, Victoria</u></p> <p>5.4.1 (d) Only a trained operator initiates an exposure session.</p> <p>In the majority of inspections undertaken within Victoria, compliance with this requirement will not be possible. In most cases, it is technically the client who initiates the exposure.</p> <p>There are three distinct variations on the setting of exposure times which have been encountered during the inspection program in Victoria.</p> <ol style="list-style-type: none"> 1. In one scenario, the exposure time is set on the tanning unit itself, usually with a digital keypad or an analogue wind up timer. We estimate in Victoria that approx. 25% of sites use this system. 2. In another scenario, the exposure time is set by the client inserting tokens into a control box adjacent to the tanning unit. These tokens are supplied by the operator, and provide a pre-programmed amount of exposure time. We estimate that approx. 15% of sites use this system. 3. In a third scenario, the exposure time is set by an operator using a central control system, usually situated at a reception desk and the session is started either on a delay timer or by the client. We estimate that approx. 65% of sites use this system. <p>The above requirement, as it is currently written, can only be satisfied by a small portion of the businesses currently employing the third system. This requirement should be re-worded to emphasise the importance of a trained operator controlling and determining the exposure time, rather than initiating the exposure, which in most cases can only be done by the client.</p> <p>In the event that RHC is of a different view, the clause still requires re-drafting to make it explicit which of these three variations is to be permitted (or</p>	<p>Changed wording to “determines and controls”.</p>

	<p>conversely not to be permitted) by jurisdictions. The current drafting is sufficiently unclear in that is highly likely that jurisdictions will take differing approaches which would potentially result in equipment in one jurisdiction being effectively banned from use until modified at a considerable cost, whilst in a neighbouring jurisdiction the same equipment might be permitted for use without modification.</p> <p>5.4.1 (g) Any exposure session does not exceed 0.9 MED</p> <p>The experience in Victoria is that '0.9 MED' is a difficult term to define in law and hence difficult to enforce in regulations. Introducing a dose related requirement incorrectly assumes that the operator has the ability to measure the dose given by a particular tanning unit. Our inspection experience and direct contact with key stakeholders has confirmed that it is not yet practical to measure the dose given by a particular tanning unit.</p> <p>The clause should be modified to require that an exposure session will not produce mild reddening or erythema of the skin.</p> <p>5.4.1 (h) Protective goggles are worn by every user...</p> <p>In line with the revised Australian Standard, the term "protective eyewear" should be used and either a description or a separate definition added which details the transmittance requirements of the protective eyewear.</p> <p>Mandatory Warning Notices</p> <p>There should be a requirement for the display of warning notices containing the information set out in the consent form, as is required in the Australian Standard.</p>	<p>The Radiation Health Committee discussed this issue and indicated that within the Glossary of Amendment No. 4 a relationship between MED and SED has been established.</p> <p>Protective eyewear has been adopted as per the Australian Standard</p> <p>Warning notices have been adopted as per the draft Australian Standards.</p>
<p>03 William B. Grant, Ph.D. Sunlight, Nutrition, and Health Research Center (SUNARC) P.O. Box 641603 San Francisco, CA 94164-1603, USA www.sunarc.org</p>	<p>My comments are primarily related to the science related to ultraviolet-B (UVB) irradiance and vitamin D production. I think that if the Amendment is truly based on health effects, not only the risks but also the benefits of UV irradiance should be considered. While it is true that vitamin D can be obtained from supplements, unless vitamin D supplementation at the rate of 1000-2000 IU/day is also encouraged, my review of the scientific literature indicates that the net health benefit of restricting use of solaria in Australia will be negative rather than positive. I also address the evidence that use of solaria leads to melanoma.</p> <p>Re: skin type.</p>	<p>Noted. While vitamin D deficiency is a significant health issue and the relationship with solar UV is noted, it should not affect policy in relation to solaria.</p>

p. 10 **Prevention of access:** Intending users who are assessed as having fair skin that will not tan (i.e. “Type 1 skin” should not be allowed to use the solarium.

I fully agree with this provision. Not only are such people at increased risk of melanoma, they do not tan well.

I have reviewed the analysis in this study:

International Agency for Research on Cancer Working Group on artificial ultraviolet (UV) light and skin cancer. The association of use of sunbeds with cutaneous malignant melanoma and other skin cancers: A systematic review. Int J Cancer. 2007 Mar 1;120(5):1116-22.

Which concluded: “Based on 19 informative studies, ever-use of sunbeds was positively associated with melanoma (summary relative risk (RR), 1.15; 95% confidence interval (CI), 1.00-1.31), although there was no consistent evidence of a dose-response relationship.”

However, if the studies from the United Kingdom, some of which did not adjust for skin type 1 participants, are removed from the analysis, the RR for ever use of sunbeds drops by 0.07-0.11 to a value that is no longer statistically significant (Table 1).

Table 1. Summary of the results of meta-analyses calculations using various sets of studies in a study I commissioned using the Cochrane Review Manager software, RevMan

Conditions	IARC study	RR, starting with original set in IARC study	RR, starting with original set in the IARC study plus*
Original set	1.15 (95% CI, 1.00-1.31)	1.20 (95% CI, 1.03-1.38)	1.21 (95% CI, 1.05-1.39)
Original set less 2 UK studies with high values		1.13 (95% CI, 0.99-1.29)	1.14 (95% CI, 1.00-1.30)
Original set less 5 UK studies		1.09 (95% CI, 0.96-1.24)	1.10 (95% CI, 0.98-1.25)
Five UK studies		2.09 (95% CI, 1.14-3.84)	

*Han J, Colditz GA, Hunter DJ. Risk factors for skin cancers: a nested case-control study within the Nurses’ Health Study. Int J Epidemiol. 2006;35:1514–21.

Thus, there is a some probability that ever use of sunbeds increases the risk of

<p>melanoma, but as pointed out by Gordon, the risk for Australians is very small and could, possibly, be related to those with skin type 1 using sunbeds when they should be excluded from such use.</p> <p>Health benefits p. 8 Gordon (2007) argues that the solarium industry is characterised by market failures, arising notably from information asymmetries. In particular, marketing activities undertaken by the industry have promoted solariums as offering health benefits, while the risks of solarium use have gone largely unacknowledged.</p> <p>I do not know what the regulations are in Australia regarding advertising the health benefits of indoor tanning using lamps that have UVB radiation. However, in Canada, Fabutan reached an agreement on vitamin D health benefits from ultraviolet irradiance:</p> <p>Fabutan and Competition Bureau reach agreement on Vitamin D health benefits from ultraviolet light</p> <p>TORONTO, Dec. 21, 2005 /CNW/ - Fabutan Sun Tan Studios, Canada's largest indoor tanning company, today announced that after a lengthy mediation session yesterday it has reached an agreement with the Competition Bureau of Canada. The agreement addresses Fabutan's ability to communicate with the public about the health benefits of Vitamin D obtained through exposure to Ultraviolet B (UVB) in a tanning bed.</p> <p>It was agreed that Fabutan may communicate that Vitamin D can be maintained or increased as a result of a tanning session in which the tanning equipment incorporates UVB irradiance. "We are extremely pleased after reviewing the scientific research that although the some of the benefits of Vitamin D are not conclusively proven, the agreement allows for us to communicate an association to the health benefits linked to Vitamin D," McNabb said.</p> <p>"Health Canada lists Vitamin D production as an effect of exposure to UVB in a tanning bed, so we felt the focus really should be on the benefits of Vitamin D. We are happy that Vitamin D finally gets its day in the sun. We commend the Competition Bureau for the open-mindedness in which I feel they approached this mediation." The agreement will be available for viewing on the Competition Bureau's web site during the first week of January.</p>	<p>Noted</p>
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"Through this process our expert witnesses provided over 1,000 pages of research supporting the benefits of Vitamin D. The body of scientific evidence supporting these claims continues to grow. Research on Vitamin D points to potential associations for the reduced risk of breast, colon, prostate, and ovarian cancer, multiple sclerosis and diabetes", McNabb said.

"I think as Canadians, we have lost sight of something very basic. The human race evolved under natural sunlight. Exposing the skin to UVB light is the way our bodies were naturally and biologically designed to produce Vitamin D," he said. "In fact, information in one of the government's own expert witness publications confirms that 85 per cent of our Vitamin D comes from exposure to UVB in sunlight. Adequate doses of UVB from natural sunlight are available to Canadians only six to eight months per year," McNabb added.

<http://www.tantalk.com/think-positive-about-uv/2353832-fabutan-competition-bureau-reach-agreement-vitamin-d-health-benefits-ultr.html>

The Amendment 4 document ignores completely the health benefit of vitamin D obtained from use of solaria. Solaria are a good source of vitamin D. With whole body exposure in a sunbed, one can produce about 10,000 IU in very few minutes: Tangpricha V, Turner A, Spina C, Decastro S, Chen TC, Holick MF. Tanning is associated with optimal vitamin D status (serum 25-hydroxyvitamin D concentration) and higher bone mineral density. *Am J Clin Nutr.* 2004 Dec;80(6):1645-9.

Porojnicu AC, Bruland OS, Aksnes L, Grant WB, Moan J. Sun beds and cod liver oil as vitamin D sources. *J Photochem Photobiol B.* 2008 May 29;91(2-3):125-31.

While it seems that many of the users of solaria are young, there are substantial health benefits from early-life ultraviolet-B irradiance for breast cancer:

John EM, Schwartz GG, Koo J, Wang W, Ingles SA. Sun exposure, vitamin D receptor gene polymorphisms, and breast cancer risk in a multiethnic population. *Am J Epidemiol.* 2007 Dec 15;166(12):1409-19.

Prostate cancer:

John EM, Koo J, Schwartz GG. Sun exposure and prostate cancer risk: evidence for a protective effect of early-life exposure. *Cancer Epidemiol Biomarkers Prev.* 2007 Jun;16(6):1283-6.

And multiple sclerosis:

van der Mei IA, Ponsonby AL, Dwyer T, Blizzard L, Simmons R, Taylor BV,

The issue of vitamin D deficiency is a concern but should not be addressed through policy on the use of solaria.

Butzkueven H, Kilpatrick T. Past exposure to sun, skin phenotype, and risk of multiple sclerosis: case-control study. *BMJ*. 2003 Aug 9;327(7410):316.

It has been reported that Australians have lower serum 25-hydroxyvitamin D levels than expected for such a sunny country:

Kimlin M, Harrison S, Nowak M, Moore M, Brodie A, Lang C. Does a high UV environment ensure adequate vitamin D status? *J Photochem Photobiol B*. 2007 Dec 14;89(2-3):139-47.

van der Mei IA, Ponsonby AL, Engelsen O, Pasco JA, McGrath JJ, Eyles DW, Blizzard L, Dwyer T, Lucas R, Jones G. The high prevalence of vitamin D insufficiency across Australian populations is only partly explained by season and latitude. *Environ Health Perspect*. 2007 Aug;115(8):1132-9.

In a study for the United States, the health benefits of UVB irradiance were found to greatly outweigh the adverse health effects of UV irradiance.

[Photochem Photobiol](#). 2005 Nov-Dec;81(6):1276-86.



[Links](#)

Comparisons of estimated economic burdens due to insufficient solar ultraviolet irradiance and vitamin D and excess solar UV irradiance for the United States.

[Grant WB](#), [Garland CF](#), [Holick MF](#).

Sunlight, Nutrition and Health Research Center (SUNARC), 2107 Van Ness Avenue, Suite 403B, San Francisco, CA 94109-2529, USA. wgrant@sunarc.org

Vitamin D sufficiency is required for optimal health, and solar ultraviolet B (UVB) irradiance is an important source of vitamin D. UVB and/or vitamin D have been found in observational studies to be associated with reduced risk for over a dozen forms of cancer, multiple sclerosis, osteoporotic fractures, and several other diseases. On the other hand, excess UV irradiance is associated with adverse health outcomes such as cataracts, melanoma, and nonmelanoma

Victoria's Sun Smart has stated:
"In Victoria average UV levels are 3 and above from the beginning of September through to the end of April. During these months, a few minutes of

skin cancer. Ecologic analyses are used to estimate the fraction of cancer mortality, multiple sclerosis prevalence, and cataract formation that can be prevented or delayed. Estimates from the literature are used for other diseases attributed to excess UV irradiation, additional cancer estimates, and osteoporotic fractures. These results are used to estimate the economic burdens of insufficient UVB irradiation and vitamin D insufficiency as well as excess UV irradiation in the United States for these diseases and conditions. We estimate that 50,000-63,000 individuals in the United States and 19,000-25,000 in the UK die prematurely from cancer annually due to insufficient vitamin D. The U.S. economic burden due to vitamin D insufficiency from inadequate exposure to solar UVB irradiance, diet, and supplements was estimated at \$40-56 billion in 2004, whereas the economic burden for excess UV irradiance was estimated at \$6-7 billion. These results suggest that increased vitamin D through UVB irradiance, fortification of food, and supplementation could reduce the health care burden in the United States, UK, and elsewhere. Further research is required to confirm these estimates.

Since this report, the health benefits of vitamin D have been extended to infectious diseases, cardiovascular diseases, and even dementia, so the benefits of UVB and vitamin D are now estimated at around \$200 billion U.S.

A study commissioned by the WHO and conducted by Australian researchers found the health benefits of solar UVB to outweigh the adverse effects by a ratio of 2000 to 1:

[Int J Epidemiol.](#) 2008 Jun;37(3):654-67. Epub 2008 Feb 14.



Comment in:

[Int J Epidemiol.](#) 2008 Jun;37(3):667-8.

Estimating the global disease burden due to ultraviolet radiation exposure.

UV exposure to the face, arms and hands or equivalent area of skin, should be enough for most people to maintain adequate vitamin D levels". Issues with solar exposure do not effect dicussions with regard to solarium use.

[Lucas RM](#), [McMichael AJ](#), [Armstrong BK](#), [Smith WT](#).

National Centre for Epidemiology and Population Health, The Australian National University, Australia. robyn.lucas@anu.edu.au

BACKGROUND: WHO's global burden of disease studies, undertaken since 1996, apportion the total global disease burden, measured in disability-adjusted life years (DALYs), to specific diseases and injuries. Recent assessments of the relative burden due to specific environmental risk factors, plus an understanding of the nature of the risk factor, may guide resource allocation in risk factor management. We report here the global disease burden due to ultraviolet radiation (UVR) exposure. METHODS: A systematic literature review identified nine diseases with sufficient evidence of a causal relationship with UVR exposure and for which the population attributable fraction (PAF) for UVR could be estimated. For cutaneous malignant melanoma and cataract, the PAF was directly applied to disease burdens already calculated by WHO. For seven other diseases, we developed population-level exposure-disease relationships and used these to calculate disease incidence and mortality, and thence disease burden. We also estimated the disease burden from rickets, osteomalacia and osteoporosis that might result if global UVR exposure was reduced to very low levels. RESULTS: UVR exposure is a minor contributor to the world's disease burden, causing an estimated annual loss of 1.6 million DALYs; i.e. 0.1% of the total global disease burden. A markedly larger annual disease burden, 3.3 billion DALYs, might result from reduction in global UVR exposure to very low levels. CONCLUSIONS: Sun protection messages are important to prevent diseases of UVR exposure. However, without high dietary (or supplemental) intake of vitamin D, some sun exposure is essential to avoid diseases of vitamin D insufficiency.

Non-melanoma skin cancer, second cancer

It should also be noted that in sunny countries, those who develop non-melanoma skin cancer have a reduced risk of developing internal cancers:

Noted, but again the research relates to solar UV exposure and vitamin D deficiency and is not a reason to alter policy on solaria.

Noted

Grant WB. An ecologic study of cancer mortality rates in Spain with respect to indices of solar UVB irradiance and smoking. *Int J Cancer*. 2007 Mar 1;120(5):1123-8.

Tuohimaa P, Pukkala E, Scélo G, Olsen JH, Brewster DH, Hemminki K, Tracey E, Weiderpass E, Kliewer EV, Pompe-Kirn V, McBride ML, Martos C, Chia KS, Tonita JM, Jonasson JG, Boffetta P, Brennan P. Does solar exposure, as indicated by the non-melanoma skin cancers, protect from solid cancers: vitamin D as a possible explanation. *Eur J Cancer*. 2007;43:1701-12.

Grant WB. The effect of solar UVB doses and vitamin D production, skin cancer action spectra, and smoking in explaining links between skin cancers and solid tumours. *Eur J Cancer*. 2008;44:12-5.

However, the same cannot be said about melanoma, since UVB irradiance is not an important risk factor for melanoma.

Health benefits of UVB and vitamin D: Reviews

The health benefits of vitamin D in reducing the risk of chronic and infectious diseases are finally being recognized scientifically. Health policy changes are expected within two year.:

[No authors listed]. Vitamin D - monograph. *Altern Med Rev*. 2008 Jun;13(2):153-64.

<http://www.thorne.com/altmedrev/.fulltext/13/2/153.pdf>

Bikle D. Nonclassic actions of vitamin D. *J Clin Endocrinol Metab*. 2008 Oct 14. [Epub ahead of print] <http://jcem.endojournals.org/cgi/rapidpdf/jc.2008-1454v1>

Bischoff-Ferrari HA, Giovannucci E, Willett WC, Dietrich T, Dawson-Hughes B. Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes. *Am J Clin Nutr*. 2006 Jul;84(1):18-28. Review. <http://www.ajcn.org/cgi/reprint/84/1/18>

Cannell J, Hollis B, Zasloff M, Heaney R. Diagnosis and treatment of vitamin D deficiency. *Expert Opin Pharmacother*. 2008 Jan;9(1):107-118.

Cannell JJ, Hollis BW. Use of vitamin D in clinical practice. *Altern Med Rev*. 2008 Mar;13(1):6-20.

<http://www.thorne.com/altmedrev/.fulltext/13/1/6.pdf>

Cherniack EP, Florez H, Roos BA, Troen BR, Levis S. Hypovitaminosis D in the elderly: from bone to brain. *J Nutr Health Aging*. 2008 Jun-Jul;12(6):366-73.

DeLuca HF. The vitamin D story: a collaborative effort of basic science and clinical medicine. *FASEB J*. 1988 Mar 1;2(3):224-36.
<http://www.fasebj.org/cgi/reprint/2/3/224>

Grant WB. Roles of solar UV radiation and vitamin D in human health and how to obtain vitamin D. *Expert Rev Dermatol*. 2007;2:563-577.

Grant WB, Holick MF. Benefits and requirements of vitamin D for optimal health: a review. *Altern Med Rev*. 2005 Jun;10(2):94-111.
<http://www.thorne.com/altmedrev/.fulltext/10/2/94.pdf>

Heaney RP. Vitamin D in health and disease. *Clin J Am Soc Nephrol*. 2008 Sep;3(5):1535-41.

Holick MF. High prevalence of vitamin D inadequacy and implications for health. *Mayo Clin Proc*. 2006 Mar;81(3):353-73.

Holick MF. Vitamin D deficiency. *N Engl J Med*. 2007 Jul 19;357(3):266-81.
content.nejm.org/cgi/content/short/357/3/266

Jablonski NG, Chaplin G. The evolution of human skin coloration. *J Hum Evol*. 2000 Jul;39(1):57-106.

Lips P. Vitamin D physiology. *Prog Biophys Mol Biol*. 2006 Sep;92(1):4-8.

Martins e Silva J. [Brief history of rickets and of the discovery of vitamin D] *Acta Reumatol Port*. 2007 Jul-Sep;32(3):205-29. Portuguese. (very interesting with some text in English)
http://www.ncbi.nlm.nih.gov/pubmed/17940496?ordinalpos=6&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Mullin GE, Dobs A. Vitamin D and its role in cancer and immunity: a prescription for sunlight. *Nutr Clin Pract*. 2007 Jun;22(3):305-22.

Norman AW. Minireview: vitamin D receptor: new assignments for an already busy receptor. *Endocrinology*. 2006 Dec;147(12):5542-8.

	<p>http://endo.endojournals.org/cgi/reprint/147/12/5542</p> <p>Norman AW. From vitamin D to hormone D: fundamentals of the vitamin D endocrine system essential for good health. Am J Clin Nutr. 2008 Aug;88(2):491S-499S.</p> <p>Rajakumar K, Thomas SB. Reemerging nutritional rickets: a historical perspective. Arch Pediatr Adolesc Med. 2005 Apr;159(4):335-41. http://archpedi.ama-assn.org/cgi/reprint/159/4/335</p> <p>Schwalfenberg, G., Not enough vitamin D: health consequences for Canadians. Can Fam Physician, 2007;53(5):841-54.</p> <p>Stumpf WE. Vitamin D and the digestive system. Eur J Drug Metab Pharmacokinet. 2008 Apr-Jun;33(2):85-100.</p> <p>Disclosure I receive funding from the UV Foundation (McLean, VA), the Vitamin D Society (Canada), and the European Sunlight Association (Brussels).</p>	
<p>04 Sue Heward Manager, SunSmart Cancer Council Victoria</p>	<p>Comments on page 2 and 3 : 5.4 Adoption of national regulatory elements for control of specified practices</p> <p>5.4.1</p> <p>(c) An assessment of skin type is conducted by a trained operator for every client before exposure in a sun-tanning unit, and that individuals with skin type 1 are not permitted to be exposed in a sun-tanning unit.</p> <p>Recommendation 1: That individuals with skin type II are also not permitted to be exposed in a sun-tanning unit.</p> <p>(g) Any exposure session does not exceed 0.9 MED, and that any repeat exposure session takes place no sooner than 48 hours after the previous exposure session.</p> <p>Recommendation 2: That the minimum time period between sessions be increased to 72 hours. See the reference</p>	<p>This has been subject of detailed discussion between industry and government representatives in the working group of the Australian Standards and it was decided not to include skin type II in the exclusions.</p> <p>This has been subject of detailed discussion between industry and government representatives on the working group of the Australian Standards and was decided to keep the 48hr time period in place.</p>

<http://ec.europa.eu/health/opinions2/en/sunbeds/1-3/5-safe-limit-sunbeds.htm#0p0> at the bottom of this webpage.

TABLE A: CONSENT FORM FOR CLIENTS OF SOLARIA CLIENT CONSENT FORM

1. Exposure to ultraviolet radiation such as from a sun-tanning unit contributes to the skin ageing process and **may cause** skin cancer.

Recommendation 3: That the words “may cause” be deleted

2. People with fair skin who are unable to tan must not use a sun-tanning unit.

Recommendation 4: Replace with a clearer statement such as People with skin type 1 (fair skin and burn easily) and will not be permitted to use a sun-tanning unit.

If it is accepted that people with skin type II are also not permitted then the statement should be: People with skin type 1 (fair skin and burn easily) and skin type II (always burns easily, tans minimally) and they will not be permitted to use a sun-tanning unit

3. Intentional sun-tanning unit exposure should be avoided for 48 hours before and after sunlight or sun-tanning unit exposure.

Recommendation 5: Time period increased to 72 hours

5. There is additional risk, and sun-tanning unit exposure is not recommended if:

- (a) you have ever been treated for solar keratoses or skin cancer; or
- (b) you have ever suffered from an abnormal reaction, or allergy, to light.

Recommendation 6: Include the following to this list

- c) have a large number of moles, freckles and/or naevi
- d) have a history of frequent childhood sunburn
- e) have a family history of melanoma
- f) have red hair or light coloured eyes (blue or green)

Agreed: Wording of new draft Standard “Exposure to ultraviolet radiation such as from a tanning unit contributes to skin cancer and skin ageing.”

Agreed to amend

Addressed in earlier comment re: skin type I & II

Addressed in the draft Australian Standard, as indicated above

Amended to be consistent with draft Australian Standard

	<p>at young people (pg 47-49)</p> <p>Cancer Council Victoria agrees that education programs aimed primarily at young people without regulation would produce smaller benefits than that the proposed regulations. The RIS states that some education campaigns are in place, this point should be clearer that these have been one-off campaigns and that currently no formal paid media or education campaign targeted at young people is being implemented in Victoria given limited resources. This is variable across Australia.</p> <p>Noting this we do also question the approach and the estimated costings outlined on page 49. They are based on a very limited didactic educational approach through schools and the estimated costs are enormous. For any such approach whether it be with or without regulations we would not recommend what has been outlined as the optimal way to design or cost such a program.</p> <p>Given we support the banning of people under the age of eighteen this is a moot point but it does raise the issue of ongoing communication and awareness for people that continue to use solariums.</p>	<p>Noted</p> <p>Noted</p> <p>Noted</p>
<p>05 Dr Mary Dingley President Cosmetic Physicians Society of Australasia</p>	<p>The Cosmetic Physicians Society of Australasia (CPSA) thanks you for the invitation to make a submission to the review of regulation of solarium. The CPSA is fully supportive of the adoption of national regulatory measures for control of solarium given the significant potential negative health impacts of tanning.</p> <p>While acknowledging that ultraviolet (UV) light under medical supervision may be useful in treating some skin conditions e.g. PUVA for vitiligo, the CPSA maintains that solarium use is generally harmful and condemns its use for all cosmetic purposes.</p> <p>Skin damage from exposure to UV light is cumulative and leads to photoageing of the skin and significantly increases the risk of skin cancer. It should be further noted that the Australian population is already at high risk of skin cancer.</p> <p>In the absence of an outright prohibition of the use of sun-tanning equipment for cosmetic purposes, we therefore support any regulation which makes adult Australians more aware of the health risks associated with the use of sun-</p>	<p>Support noted</p>

	<p>tanning equipment and bans the provision of tanning to people of fair skin who are unable to tan naturally. We also support the requirement for appropriate training in the operation of sun-tanning units and restrictions on exposure.</p>	
<p>06 Simon Critchley Director Radiation Health Unit Department of Health Queensland</p>	<p>Thank you for the invitation to the Director-General to make a submission about the <i>National Directory for Radiation Protection – Draft Amendment No. 4, 2008 – Solaria</i> and accompanying draft <i>Regulatory Impact Statement</i>. The Director-General has asked me to respond on his behalf.</p> <p>Queensland supports the initiative to regulate the solaria industry and impose nationally uniform requirements on this industry.</p> <p>I appreciate that the intent of the Amendment is to provide an overarching legislative framework which each jurisdiction must implement according to its own drafting requirements. It is therefore important that the information proposed to be included in the National Directory is unambiguous and provides as much clarity as possible to ensure that each jurisdiction can develop an appropriate and workable legislative model within their respective legislation to ensure uniform outcomes are achieved in each jurisdiction. An important aspect of this is to ensure that the intended measures are able to be enforced.</p> <p>With this in mind, Queensland Health has considered the <i>Draft Amendment No. 4 Solaria</i>, and the accompanying draft <i>Regulatory Impact Statement</i>, and has identified some issues that need to be resolved before Queensland can support the proposed <i>National Directory for Radiation Protection – Draft Amendment No. 4, 2008 – Solaria</i>. The issues are as detailed below.</p> <p>1. General comment – nomenclature</p> <ul style="list-style-type: none"> Section 5.4.1 refers to the standard NDRP term of ‘Responsible Person’. In this context, the meaning of the term is well understood. However, throughout the proposed amendment, mention is made of some other persons and it is somewhat unclear, in the context of the NDRP, who these persons are meant to be. It is imperative that there be clarity in the description of these persons and in the intent and definition of their roles in order that responsibilities are clearly and unambiguously assigned to the correct persons. The other persons are ‘person supervising the operation of a sun-tanning unit’ and ‘trained operator’. The problem with the existing references to these other persons is compounded by the fact that the 	<p>Support noted</p> <p>Noted</p> <p>Agreed to amend for clarity purposes.</p>

	<p>terms will be used in the context of the NDRP where the concept of a 'trained operator' already exists, but the concept of the 'person supervising the operation of a sun-tanning unit' does not.</p> <p>2. Clause 5.4.1(b)</p> <ul style="list-style-type: none"> This clause details the training requirements of persons supervising the operation of a sun-tanning unit. We are of the opinion that this training should also cover the health risks associated with the use of solarium. This is particularly important as it may assist in resolving some of the issues relating to false claims being made by the solarium operators. <p>3. Clause 5.4.1(b) (i)</p> <ul style="list-style-type: none"> This clause requires persons supervising the operation of a sun-tanning unit to be trained in the requirements of the relevant Australian Standards and their practical implementation. It is not appropriate to merely reference 'relevant Australian Standards' in this context because it is unclear which Australian Standards are intended to be the relevant ones. This clause needs to be more specific. <p>In any case, it is inappropriate in any legislative instrument to refer as a requirement to the specification of an Australian Standard which might change without reference to the Parliament. As it happens, AS/NZS 2653 is currently being revised and thus nobody can be sure of the specific content of the new Standard and specifically for this clause, to the training requirements therein. The proposed amendment to the NDRP must clearly state the actual outcomes we intend jurisdictions to ensure are achieved in the training of persons. To clarify, Queensland requires any requirements to be specifically detailed in the NDRP amendment so that we can be absolutely and unambiguously clear about the outcomes we need to achieve in our legislation.</p> <p>4. Clause 5.4.1(b) (ii)</p> <ul style="list-style-type: none"> It would appear that this clause requires a trained operator to be trained in the determination of skin types. The skin typing methodology the person meant to be trained in must be specified to ensure consistency across businesses and across the country. At present, it is unclear which skin typing methodology is intended to be followed. 	<p>Agreed</p> <p>Agreed</p> <p>This is done in the item 5.4.1(b)(i)-(iii)</p> <p>Agreed: The Fitzpatrick Skin Photo Typing Scheme is the one that is used in the Australian Standard and will be specified here.</p>
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	<ul style="list-style-type: none"> • It would also appear that this clause requires a trained operator to be trained in the determination of exposure times. This could be quite problematic. A study undertaken this year by Queensland Health has revealed that the erythematous UV irradiance measured along the axis of a number of sun-tanning units ranged from 1.4 to 49.6 SED/h. Consequently, the determination of exposure times would necessitate that a trained operator be also trained in the determination of exposure rates in each machine. Clearly, this would be impractical and beyond the capability of those persons the market has typically trained as operators in the past. • The purpose for requiring the Responsible Person to ensure a trained operator is trained in the determination of skin types and exposure times is unclear. It is clear that someone must be trained sufficiently to ascertain whether a prospective client is under the age of 18 years and to determine on behalf of the Responsible Person whether a prospective client has skin type 1 so that the Responsible Person's interests are protected. However, it is unclear why the trained operator should be required to perform other skin typing assessments or to determine exposure times, unless the trained operator is going to be expected to determine the dose of UV radiation given to a client. Should this be the case, this would mean that the trained operator would need some significant knowledge and competency in making UV dose assessments and, in the Queensland context, it would probably mean the trained operator would be required to hold a use licence as they would be affecting the exposure of the client. If this is not the case, the Responsible Person should be made to ensure that an exposure-time chart for their particular equipment is developed and followed by the trained operator. <p>5. Clause 5.4.1(f)</p> <ul style="list-style-type: none"> • This clause refers to the requirement for a consent form to be completed by the client. The exact purpose of the form is not clear. Is its purpose to ensure that the operator advises the client that there are risks associated with the use of solarium and that the client ought to carefully consider the risk it poses to them or is its purpose an attempt to seek the informed consent of the client in an attempt to ensure the legal liability following the injury of a client rests with the client? 	<p>Clearly, shortcut methods such as use of exposure charts etc would resolve this issue.</p> <p>The length of exposure is related to skin type, so some basic knowledge and use of exposure charts etc is required</p> <p>RHC discussed and agreed it should remain a consent form</p>
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	<p>What constitutes 'informed consent' is well established in law and such a requirement in the National Directory could be misleading for operators and users. That is, an operator may think they have obtained the proper level of consent but if a case were to proceed to court, then the legal definition of what constitutes informed consent would apply.</p> <p>We suggest that the form should be an information document, with the individual signing that they have read and understood the information provided. It is also a means of providing documented evidence that the obligation on the responsible person to provide this minimal information to the client has been fulfilled. It is therefore suggested that a more appropriate term be 'information form'.</p> <p>6. Additional requirements</p> <p>There are some additional measures which we believe ought to be included in the regulatory elements mentioned in the proposed amendment to the NDRP. These are as follows.</p> <ul style="list-style-type: none"> • It is important that appropriate warning notices are conspicuously displayed at each solarium. As this is an important responsibility of the Responsible Person, this requirement should be included under section 5.4.1. • The Regulatory Impact Statement refers to the licensing of solarium operators. If this is required, section 5.4.1 should impose an additional requirement that the Responsible Person must hold an appropriate authorisation (e.g. a licence) from the relevant regulatory authority. This would also assist in achieving uniformity in the requirements across the jurisdictions. • Neither the Regulatory Impact Statement nor the proposed amendment to the NDRP have any reference to the requirement for Responsible Persons to ensure appropriate maintenance of the equipment and the necessity to ensure constancy of UV output for each sun-tanning unit, particularly in the light of my discussion in item 4, dot point 3 above. This issue must be addressed in the proposed amendment. <p>7. Amendment to Schedule 2 – Categories of Non-Ionizing Radiation</p>	<p>Agreed</p> <p>Authorisations are in Section 4 of the NDRP</p> <p>Both the national forum on solarium and the RHC had agreed not to consider equipment requirements at this time.</p>
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	<ul style="list-style-type: none"> • This schedule lists the non-ionizing radiation apparatus that requires regulatory control, and it is proposed that ‘a solarium used for cosmetic purposes’ be such an apparatus. The proposed definition of ‘solarium’ relates to it being a commercial establishment containing one or more sun-tanning units. It is therefore the sun-tanning units that are producing the non-ionizing radiation, not the solarium. Consequently, the Amendment to Schedule 2 – Categories of Non-Ionizing Radiation should reference ‘sun-tanning units used for cosmetic purposes’, as this is what should be subject to the regulatory controls, rather than the establishment housing such units. <p>8. Glossary</p> <ul style="list-style-type: none"> • The definition of MED – Minimum Erythral Dose refers to both skin type 1 and skin type 4. While it is noted that skin type 1 is defined in the glossary, skin type 4 is not. Skin type 4 needs to be either defined or removed from the definition of MED – Minimum Erythral Dose. Additionally, the reference to skin type 1 must also include a reference to the skin typing methodology to be used. • The definition of Supervision needs to be changed to ensure that the exposure time aspect is adequately incorporated in the definition. This could be achieved by changing the existing definition to ‘...exposure session is terminated in the intended time.’. • The term ‘cosmetic procedures’ needs to be defined to clarify that it does not include reference to therapeutic medical procedures. • The term ‘commercial establishment’ needs to be defined because a medical practitioner’s premises may not be considered a commercial establishment but it might still include a sun-tanning unit being operated for cosmetic purposes. <p>For your information, Queensland has recently amended its <i>Radiation Safety Act 1999</i> to provide the head of power to prohibit commercial solarium operators from allowing persons under 18 to be exposed in sun-tanning units. I expect that this will become effective from March 2009 once the necessary change to the <i>Radiation Safety Regulation 1999</i> has been made.</p> <p>Please do not hesitate to contact Ms Paula Veevers, Assistant Director, on</p>	<p>Amended</p> <p>All skin types are now defined</p> <p>Agreed: Fitzpatrick scheme to be used.</p> <p>RHC agreed that cosmetic procedures and commercial establishment did not need to be defined here</p> <p>Noted</p>
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	Ph: 07 3406 8014, if you wish to discuss these changes in more detail.	
<p>07 Kay Coppa Manager Skin Cancer Prevention Unit Cancer Council NSW</p>	<p style="text-align: center;">National Directory for Radiation Protection Amendment No. 4, 2008-11-14 SOLARIA – Consultation Draft – 17 October 2008-11-14 Comments – Cancer Council NSW</p> <p>Comments on page 2 and 3 : 5.4 Adoption of national regulatory elements for control of specified practices 5.4.1 (b) Any person supervising the operation of a sun-tanning unit is trained in the following:</p> <ul style="list-style-type: none"> (i) The requirements of relevant Australian Standards and their practical implementation; (ii) Determination of skin types and exposure times; (iii) Screening for potentially exposure limiting conditions (iv) Emergency procedures in case of over-exposure to UV light; (v) Types and wavelength of UV light; (vi) Procedures for sanitizing protective eye wear and tanning equipment. <p>Recommendation 1: That any person supervising the operation of a sun-tanning unit has competency in complying with relevant state regulations.</p> <p>(c) An assessment of skin type is conducted by a trained operator for every client before exposure in a sun-tanning unit, and that individuals with skin type 1 are not permitted to be exposed in a sun-tanning unit.</p> <p>Recommendation 2: That individuals with skin type II are also not permitted to be exposed in a sun-tanning unit.</p> <p>(g) Any exposure session does not exceed 0.9 MED, and that any repeat exposure session takes place no sooner than 48 hours after the previous exposure session.</p> <p>Recommendation 3: That the minimum time period between sessions be increased to 72 hours.</p>	<p>Each jurisdiction will require operators to comply with their regulations</p> <p>This has been discussed by the working group of the Australian Standards and it was decided not to include skin type II in the exclusions.</p> <p>This has been discussed by the working group of the Australian Standards and it was decided to keep the 48hr time period in place.</p>

TABLE A: CONSENT FORM FOR CLIENTS OF SOLARIA

1. Exposure to ultraviolet radiation such as from a sun-tanning unit contributes to the skin ageing process and may cause skin cancer.

Recommendation 1: Exposure to ultraviolet radiation such as from a sun-tanning unit contributes to the skin ageing process, melanoma and other skin cancers.

2. People with fair skin who are unable to tan must not use a sun-tanning unit.

Recommendation 2: People with skin type 1 (fair skin and burn easily) are not permitted to use a sun-tanning unit.

If it is accepted that people with skin type II are also not permitted then the statement should be: People with skin type 1 (fair skin and burn easily) and skin type II (always burns easily, tans minimally) are not permitted to use a sun-tanning unit

3. Intentional sun-tanning unit exposure should be avoided for 48 hours before and after sunlight or sun-tanning unit exposure.

Recommendation 3: Time period between exposures be increased to 72 hours

5. There is additional risk, and sun-tanning unit exposure is not recommended if:

- (a) you have ever been treated for solar keratoses or skin cancer; or
- (b) you have ever suffered from an abnormal reaction, or allergy, to light.

Recommendation 4: Include the following to this list

- c) have a large number of moles, freckles and/or naevi
- d) have a history sunburn
- e) have a family history of melanoma or other skin cancers
- f) have red hair or light coloured eyes

Statement that requires client signature

Agreed: Wording of new draft Standard “Exposure to ultraviolet radiation such as from a tanning unit contributes to skin cancer and skin ageing.”

Noted: previously addressed

Noted: previously addressed

Amended to be consistent with draft Australian Standard

	<p>Recommendation 5: Adjustment of the statement to be; I,: -am aged 18 years or over Y/N -acknowledge that the trained operator has made an assessment of my skin type Y/N - have carefully read and fully understand the above information and choose to undergo ultraviolet exposure in this establishment. Y/N</p> <p>Glossary</p> <p>Recommendation 6: Definition of all skin types be included in the glossary.</p> <p>Comment on National Directory for Radiation Protection: Amendment No.4 Solaria</p> <p>Recommendation 1: Cancer Council NSW recommends the adoption of the NDRP Amendment No. 4 (Solaria) and that the propped amendment contain the following substantive elements:</p> <ul style="list-style-type: none"> ▪ Prohibition on persons under 18 years of age using sun-tanning units; ▪ All exposures to sun-tanning units to be subject to the supervision by an operator; ▪ All persons supervising the operation of the sun-tanning units be trained; ▪ Only such trained persons to initiate exposures; ▪ Skin type to be assessed by operators and persons with skin type I to be prohibited from using sun-tanning units; and ▪ Clients to provide written consent before using a sun-tanning unit; and ▪ Specified limit on exposure in an individual session and on minimum time between successive sessions. <p>Recommendation 2: people with skin type II are also not permitted to be exposed in a sun-tanning unit.</p> <p>Comment on alternatives to the proposed amendment</p> <p>Alternative 1: Under the current Australian/New Zealand Standard on Solaria for cosmetic purposes (AS/NZ 2635:2002) people aged 16 – 17 years currently require parental permission to access solaria. A number of Australian studies indicate that voluntary compliance with this requirement is poorly enforced.</p>	<p>Agreed</p> <p>Agreed</p> <p>This has been discussed by the working group of the Australian Standards and was decided not to include skin type II in the exclusions</p>
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	<p>Alternative 1 is not recommended by Cancer Council NSW.</p> <p>Alternative 2: People with skin type I are at high risk of skin damage and skin cancer from UV radiation, including artificial sources of UV radiation in solaria.</p> <p>Alternative 2 is not recommended by Cancer Council NSW.</p> <p>Alternative 3: The Australian/New Zealand Standard on Solaria for cosmetic purposes (AS/NZ 2635:2002) is a <u>voluntary code of practice</u> designed to provide owners/operators of solaria with generic guidelines to improve safety, for operators and users of solaria. Numerous studies show that voluntary compliance with Standard requirements is poorly enforced. These requirements include recommendations to reduce use of sun-tanning units by vulnerable groups such as people aged 15 to 18 years and people with Skin Type 1.</p> <p>While bodies such as the Cancer Council will continue to warn people on the risks of solaria, education campaigns do not replace the need for increased safety by regulation.</p> <p>Alternative 3 is not recommended by Cancer Council NSW.</p> <p>Page 9, footnote11: “Research indicates that exposure to UV radiation does not affect risk levels for Basal Cell Carcinoma, the other major category of skin cancer.” Current research strongly suggests that around 99% of BCC in Australia are attributable to sun exposure.</p>	<p>Noted</p> <p>Noted</p> <p>Noted</p> <p>Agreed to amend</p>
<p>08 Kerry O’Hare Manager, Sunsmart Cancer Council WA</p>	<p>Thank you for the opportunity to comment on the draft Amendment No. 4 – Solaria to the National Directory for Radiation Protection.</p> <p>In addition to supporting the submissions and recommendations made by other state Cancer Council’s, please find enclosed additional comments for your consideration.</p> <p>The Cancer Council WA recommends the adoption of Amendment No. 4 with the additional consideration to restrict access for skin type I and II, and to extend any repeat exposure from 48 hours to 72 hours after the previous exposure.</p>	<p>This has been discussed by the working group of the Australian Standards and was decided not to</p>

	<p>Solaria regulation that prohibits people under 18 years of age from using solarium has recently been introduced in Western Australia. Adoption of Amendment No. 4 would strengthen current regulatory efforts and provide uniform requirements for control of solarium throughout Australia.</p> <p>National Directory for Radiation Protection Amendment No 4 – Solarium Comments – Cancer Council WA</p> <p>5.4.1 (B) Any person supervising the operation of a sun-tanning unit is trained in the following...</p> <p><i>Recommendations:</i></p> <ol style="list-style-type: none"> 1. Ensure personnel supervising operations have competency to comply with regulations and operational guidelines. 2. B (iii) Screening for potential exposure limiting conditions, including proof of age. <p>5.4.1 (C) An assessment of skin type is conducted by a trained operator for every client before exposure in a sun-tanning unit and that individuals with skin type I are not permitted to be exposed in a sun-tanning unit.</p> <p><i>Recommendations:</i></p> <ol style="list-style-type: none"> 3. Consumers are informed of the definition of skin type I and II. 4. Individuals with skin type I and II are not permitted to use solarium. <p>5.4.1 (G) Any exposure session does not exceed 0.9 MED, and that any repeat exposure session takes place no sooner than 48 hours after the previous exposure session.</p> <p><i>Recommendation:</i></p> <ol style="list-style-type: none"> 5. That any repeat exposure takes place no sooner than 72 hours after the previous exposure. <p>Table A: Client Consent Form</p> <p><i>Recommendations:</i></p> <ol style="list-style-type: none"> 6. The consumer consent form should be written in plain English and pre-tested to ensure it is easily understood by a range of consumers, including those who speak English as a second language. 7. (1) Amend introductory statement - <i>Research shows that exposure to ultraviolet</i> 	<p>include skin type II in the exclusions.</p> <p>Noted</p> <p>Agreed: RHC acknowledged that an outcome of the operators training should be; that skin types are adequately assessed.</p> <p>It is not agreed to exclude skin type II, which is consistent with Australian Standards</p> <p>Discussed in development of the draft Australian Standard, but not included in the Standard or here.</p> <p>Noted</p> <p>Amended</p>
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	<p><i>(UV) radiation such as from a sun-tanning unit contributes to the skin aging process and an increased risk of developing skin cancer.</i></p> <p>8. (2) Include statement advising consumers that people under the age of 18 and those with fair skin that burns easily and slightly tans after repeated exposures should not use solaria due to increased risk of developing skin cancer.</p> <p>9. (3) Increase time period between sessions to 72 hours.</p> <p>10. (5) List additional risk factors as also highlighted by other Cancer Councils, including:</p> <ul style="list-style-type: none"> • a large number of moles, freckles and/naevi • history of sunburn, especially as a child • family history of skin cancer • fair/red hair and/or light coloured eyes. <p>11. Encourage consumers to seek medical advice if there is any general concern/doubt about the use of solaria, not just concern regarding Items 2, 5 or 6.</p> <p>12. Include checklist for consent as recommended by the Cancer Council NSW to confirm consumer:</p> <ul style="list-style-type: none"> • is 18 years or over • has had skin type assessment undertaken by trained operator • has read and understood information contained in the consent form. <p>Glossary <i>Recommendations:</i></p> <p>13. Include plain English definition of skin type II.</p> <p>14. Consider replacing abbreviated “UVR” with UV radiation.</p> <p>15. Consider reviewing definition of supervision to include being on the premises to ensure that all pre-exposure requirements are fulfilled, exposure session is adequately monitored and terminated.</p> <p>Footnote <i>Recommendation:</i></p> <p>16. Review and amend statement to reflect current research.</p>	<p>Skin type I and under 18 are prohibited so statement is unnecessary Not agreed for consistency with Australian Standard Not agreed for consistency with Australian Standard</p> <p>Not appropriate for this regulatory instrument</p> <p>Agreed</p> <p>All skin types now defined Agreed</p> <p>Definition amended</p> <p>Assume this refers to footnote 11 in RIS. Amended</p>
<p>09 Lawson Ride Chief Executive Officer, Cancer Council Tasmania</p>	<p>Cancer Council Tasmania wishes to thank ARPANSA for the opportunity to make a Submission to the National Directory for Radiation Protection Amendment No. 4, 2008, Solaria’.</p> <p>As the invitation did not reach many of us in various state Cancer Councils throughout Australia until just a week or two ago, we very much appreciate the granting of an extension for this submission.</p> <p>Please find our Submission document attached.</p>	

	<p>Used for Cosmetic Purposes, and the Cancer Council Australia. This is an important step and is supported fully by Cancer Council Tasmania.</p> <p>The development of legislation and increased regulatory control of solaria operations is also endorsed. Thus in general terms the proposed Amendment No.4 is supported by Cancer Council Tasmania, but with suggestions for further improving the safety of these strategies even further.</p> <p>With reference to the accompanying draft Regulatory Impact Statement (RIS) which has informed the choice of the current Amendment No. 4 we note that our preferred option of the Proposed NDRP amendment <u>with</u> the addition of a broad public education campaign on the risks of solaria use was not one of the options considered in a cost-benefit analysis. We believe the combination of approaches may have improved the benefits substantially beyond what could be achieved by regulation alone and may have been able to change the perceptions and behaviour of a much broader audience.</p> <p>However even within the current proposed Amendment there are a number of points for further consideration.</p> <p><u>Cancer Council Tasmania:</u></p> <ul style="list-style-type: none"> • Is concerned that the reliance upon determination of skin types in permitting exposure is inadequate especially as only skin type 1 is proposed for exclusion. We note that both skin types 1 and 2 always require skin burning in order that a tan is developed and that skin type 3 sometimes requires burning. The International Commission of Non-Ionising Radiation Protection “concluded that an increased risk of skin cancer was particularly high for ... people having skin phototypes 1 and 2”. • Considers that barriers to implementation and enforcement of operator training, installation of timing devices and the requirement that operator to remain present to totally supervise a session will need to be overcome by the industry and the enforcement agencies in order that health risk is reduced to an acceptable level. • Considers the client consent form may help to protect an operator or business from litigation but does not suffice as informed consent without the context of a broader public education campaign, and asks whether given the known risk of exposure whether even ‘regulations’ would stand up in court as being sufficiently protective. • Is concerned that solaria operators may experience a conflict of interest in 	<p>Support noted</p> <p>Noted</p> <p>Noted as previously indicated to other cancer councils.</p> <p>Training modules to meet regulatory requirements are in development</p> <p>Noted</p>
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	<p>refusing people a service and may be tempted for example to deem a person as skin type 2 not skin type 1 etc. The Australian College of Dermatologists has already commented on the industry's 'demonstrated lack of capacity for self-regulation'.</p> <ul style="list-style-type: none"> • Emphasises that the recent recommendations regarding safe sun exposure for adequate vitamin D production throughout the year are set at one third of an MED. We therefore caution that 0.9 of an MED is so close to sunburn, as to be both difficult to judge effectively and not particularly protective of the client. • Warns that Claire Oliver, a young woman who died only last year of melanoma, was not of skin type 1. <p>The Cancer Council Tasmania therefore recommends:</p> <p>An endorsement of the proposed Amendment but with the following changes to better address the concerns outlined above, and to be more in line with recommended changes to the Draft Australian and New Zealand Standard 'Solaria for cosmetic purposes'.</p> <ol style="list-style-type: none"> 1. A broad community education campaign warning of the dangers of solaria use for cosmetic purposes. 2. That we support a ban on use by people under 18, especially on the grounds of greater vulnerability and consent issues. 3. That in item 5.4.1(b)(iii) the wording be changed to 'Screening for potentially exposure limiting conditions and appropriate modification of treatment or rejection of high risk clients.' 4. That in item 5.4.1(c) the wording be changed to ...“that individuals with skin types 1 or 2 are not permitted to be exposed in a sun-tanning unit.” 5. That in item 5.4.1(d) words be added so that 'Only a trained operator initiates an exposure session, and is responsible for setting and controlling the exposure time and for constant supervision of the session.' 6. Regarding 5.4.1(f) that further thought should be given to the meaning of informed consent given the self-motivation of a client seeking a tan in the first place and the lack of meaningful risk awareness. That perhaps specific risks should be outlined on the consent form such as the apparent 75% increase in 	<p>Comment noted, but this is not a self-regulation proposal.</p> <p>Noted</p> <p>Noted</p> <p>Endorsement noted</p> <p>Support noted</p> <p>Disagreed to remain consistent with Australian Standards</p> <p>Disagreed – consistent with Australian Standards, skin type II are not to be excluded.</p> <p>Already covered by (d) and (e)</p> <p>Noted but no amendment made</p>
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	<p>the risk of melanoma for those who first use a solarium under the age of 30!</p> <p>7. Regarding 5.4.1(g) that 0.9 of an MED is so close to sunburn that it is not particularly protective of the client and cannot be guaranteed to be safe. There should be a 'Warning:' here to clients along the lines that 'N.B. Recent recommendations regarding safe sun exposure and vitamin D advise that no UV levels of 3 or above are safe and that safe sun exposure throughout the year is set at one third (0.33) of an MED. We therefore caution that 0.9 of an MED is very close to sunburn, is difficult to judge effectively and cannot be considered safe!' Also change the repeat exposure times to 'no sooner than 72 hours after the previous exposure'</p> <p>8. Further that under the issue of client consent it should be very clearly pointed out via an additional 'Warning:' to clients that 'The risks of Solaria use are sufficiently serious to emphasise that existing Standards and Regulations are designed to reduce the risks of utilising tanning equipment but are NOT an assurance that such procedures are safe.'</p> <p>9. That the proposed Client Consent form (Table A) need to be changed to be in line with the latest Draft Australian Standards which also specify that warning signs in cubicles are needed as outlined in the Draft Australian Standards and further comments to these as described here. (See Appendix A below)</p> <p>10. That in the existing proposed client consent form (Table A), the descriptions of items 2 and 6 in particular are inadequate. Item 2 should be accompanied by visual and written descriptions of skin types for clients' consideration and should spell out that people with skin types 1 and 2 must/should not use a sun-tanning unit. Item 6 needs to be specific regarding certain medications and cosmetics. It should spell out 'There may be further risk of sun-tanning unit exposure if you are...(please put a tick beside any of the following that apply): a) pregnant b) taking any of the following medications or using any of the following cosmetics (followed by a list)</p> <p>11. Item 3 in the existing proposed client consent form (Table A) should be changed from 48 to 72 hours.</p> <p>12. That if proper screening is to occur as indicated in 5.4.1(b)(iii) it would be desirable to spell out that proper screening should exclude clients at high risk</p>	<p>Comment noted but no change made</p> <p>Disagreed for consistency with Australian Standards</p> <p>Disagreed to maintain a form of words more consistent with the Australian Standards</p> <p>A requirement for warning signs has been included</p> <p>More general statements are preferred as a list will no doubt be out of date quickly and it is not agreed to exclude skin type II, for consistency with Australian Standards</p> <p>Disagreed for consistency with Australian Standards</p> <p>Amended to reflect list in draft Australian Standard</p>
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	<p>due to one or more of the key risk factors under point 5 on the existing proposed form. See a more comprehensive list in Draft Australian Standards (Appendix A below) as mentioned above which should be included in this version.</p> <p>13. Under the Glossary section please explain this in more straight forward terms, or should the sentence at least read ‘...with the erythematous effectiveness as determined/set/measured by the CIE across...’ rather than ‘...effectiveness of the CIE...’?</p> <p>References:</p> <p>Draft for Public Comment Australia/New Zealand Standard (2008), Solaria for cosmetic purposes DR 0814, Revision of AS/NZS 2635:2002 International Agency for Research on Cancer (2006) Sunbed use in youth unequivocally associated with skin cancer, Press Release no. 171, 29 November</p> <p>Public and Environmental Health Service DHHS (2008) Solaria in Tasmania: Options for Regulating, Discussion Paper</p> <p>The Cancer Council Australia (2007) National Cancer Prevention Policy 2007-09</p> <p>www.skincancer.org/prevention/skin-types-and-at-risk-groups.html</p> <p>APPENDIX A:</p> <p>DRAFT ONLY DR08141.doc - 04/06/2008</p> <p>3.5 CLIENT INFORMATION 3.5.1 Warning notices One or more warning notices, each with minimum dimensions of 21 cm × 30 cm (i.e. minimum A4 paper size) shall be placed so as to be within immediate view of every client entering any commercial establishment and in each sun-tanning unit cubicle. The following information must be included in the notices, in legible print (i.e. the heading not less than 36 pt in Arial, text not less than 32 pt in Arial):</p>	<p>Amended</p>
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(a) Sun tanning units emit ultraviolet radiation.
 (b) Exposure to ultraviolet radiation contributes to skin ageing and skin cancer.
 (c) Repeated exposure further increases risk.
 (d) People with fair skin (Skin Photo Type I) who burn easily will not be permitted to use a sun-tanning unit.
 (e) Further intentional exposure to sunlight or sun-tanning unit must be avoided for the next 48 hours.
 (f) Protective goggles must be worn at all times while undergoing sun-tanning unit exposure.
 (g) No person under the age of 18 is permitted to use a sun-tanning unit.

3.5.2 Client consent form
 Prior to the commencement of a course of tanning at a commercial establishment of one or more sun-tanning unit exposure sessions, the solarium operator shall ensure that a consent form as set out in Appendix A is handed to the client.
 The solarium operator shall further ensure the following:

(a) That the client signs and dates the form.
 (b) That the client returns the signed and dated form prior to commencement of first tanning session in the establishment.
 (c) That the original signed and dated form is filed in the records of the establishment for a period of not less than 2 years.
 (d) That a copy of the signed and dated form is handed to the client.

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 Storage, distribution or use on network prohibited.

DRAFT ONLY 12 DRAFT ONLY
 DR08141.doc - 04/06/2008
 CONSENT FORM FOR CLIENT OF A COMMERCIAL ESTABLISHMENT
 (Normative)
 CLIENT CONSENT FORM
 Please read the following information carefully:

1 Exposure to ultraviolet radiation such as from a sun-tanning unit contributes to the skin ageing process and skin cancer.
 2 Intentional sun-tanning unit exposure should be avoided for 48 hours before and after sunlight or sun-tanning unit exposure.
 3 Protective goggles must be worn at all times while undergoing sun-tanning unit exposure.
 4 If you have fair skin and burn easily you will not be permitted to use a sun-

	<p>tanning unit. 5 There is additional risk, and sun-tanning unit exposure is not recommended if you— (a) have ever been treated for solar keratoses or skin cancer; (b) have a large number of moles, freckles and/or naevi; (c) have a history of frequent childhood sunburn; (d) burn easily; or (e) have ever suffered from an abnormal reaction, or allergy, to light. 6 There may be further risk if you are pregnant, taking certain medications by mouth or applying medications or certain cosmetics to the skin. If there is any doubt in your mind in relation to any of the particulars described in Items 2, 5 and 6 above, consult your doctor before undergoing any ultraviolet exposure. I am over the age of 18, and I, have carefully read and fully understand the above information and choose to undergo ultraviolet exposure in this establishment. WARNING NOTES: 1 Sun-tanning units emit ultraviolet radiation. 2 Exposure to ultraviolet radiation contributes to skin ageing and skin cancer. Repeated exposure increases risk. 3 People with fair skin who burn easily will not be permitted to use a sun-tanning unit. 4 Further intentional exposure to sunlight or sun-tanning unit should be avoided for the next 48 hours. 5 Protective goggles must be worn at all times while undergoing sun-tanning unit exposure. 6 No person under the age of 18 is permitted to use a sun-tanning unit. Signed:..... Date: Name of establishment: Licensed to</p>	
<p>10 John Piispanen A/Senior Director Environmental Health Branch Queensland Health</p>	<p>Thank you for the invitation to the Director-General to make a submission about the <i>National Directory for Radiation Protection - Draft Amendment No. 4, 2008 - Solaria</i> and accompanying draft Regulatory Impact Statement. The Director-General has asked me to respond on his behalf.</p> <p>Queensland supports the initiative to regulate the solarium industry and impose nationally uniform requirements on this industry.</p>	<p>Support noted</p>

	<p>3. Clause 5.4.1(b) (i)</p> <ul style="list-style-type: none"> This clause requires persons supervising the operation of a sun-tanning unit to be trained in the requirements of the relevant Australian Standards and their practical implementation. It is not appropriate to merely reference `relevant Australian Standards' in this context because it is unclear which Australian Standards are intended to be the relevant ones. This clause needs to be more specific. <p>In any case, it is inappropriate in any legislative instrument to refer as a requirement to the specification of an Australian Standard which might change without reference to the Parliament. As it happens, AS/NZS 2653 is currently being revised and thus nobody can be sure of the specific content of the new Standard and specifically for this clause, to the training requirements therein. The proposed amendment to the NDRP must clearly state the actual outcomes we intend jurisdictions to ensure are achieved in the training of persons. To clarify, Queensland requires any requirements to be specifically detailed in the NDRP amendment so that we can be absolutely and unambiguously clear about the outcomes we need to achieve in our legislation.</p> <p>4. Clause 5.4.1(b) (ii)</p> <ul style="list-style-type: none"> It would appear that this clause requires a trained operator to be trained in the determination of skin types. The skin typing methodology the person meant to be trained in must be specified to ensure consistency across businesses and across the country. At present, it is unclear which skin typing methodology is intended to be followed. It would also appear that this clause requires a trained operator to be trained in the determination of exposure times. This could be quite problematic. A study undertaken this year by Queensland Health has revealed that the erythema UV irradiance measured along the axis of a number of sun-tanning units ranged from 1.4 to 49.6 SED/h. Consequently, the determination of exposure times would necessitate that a trained operator be also trained in the determination of exposure rates in each machine. Clearly, this would be impractical and beyond the capability of those persons the market has typically trained as operators in the past. 	<p>Agreed and amended</p> <p>The outcomes are specified in 5.4.1(b) (i) – (viii)</p> <p>Now clarified</p> <p>The operator must be able to determine exposure time. Use of exposure charts etc should assist in meeting this requirement</p>
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	<ul style="list-style-type: none"> The purpose for requiring the Responsible Person to ensure a trained operator is trained in the determination of skin types and exposure times is unclear. It is clear that someone must be trained sufficiently to ascertain whether a prospective client is under the age of 18 years and to determine on behalf of the Responsible Person whether a prospective client has skin type 1 so that the Responsible Person's interests are protected. However, it is unclear why the trained operator should be required to perform other skin typing assessments or to determine exposure times, unless the trained operator is going to be expected to determine the dose of UV radiation given to a client. Should this be the case, this would mean that the trained operator would need some significant knowledge and competency in making UV dose assessments and, in the Queensland context, it would probably mean the trained operator would be required to hold a use licence as they would be affecting the exposure of the client. If this is not the case, the Responsible Person should be made to ensure that an exposure-time chart for their particular equipment is developed and followed by the trained operator. <p>5. Clause 5.4.1(f)</p> <ul style="list-style-type: none"> This clause refers to the requirement for a consent form to be completed by the client. The exact purpose of the form is not clear. Is its purpose to ensure that the operator advises the client that there are risks associated with the use of solarium and that the client ought to carefully consider the risk it poses to them or is its purpose an attempt to seek the informed consent of the client in an attempt to ensure the legal liability following the injury of a client rests with the client? <p>What constitutes 'informed consent' is well established in law and such a requirement in the National Directory could be misleading for operators and users. That is, an operator may think they have obtained the proper level of consent but if a case were to proceed to court, then the legal definition of what constitutes informed consent would apply.</p> <p>We suggest that the form should be an information document, with the individual signing that they have read and understood the information provided. It is also a means of providing documented evidence that the obligation on the responsible person to provide this minimal information to the client has been fulfilled. It is therefore suggested that a more appropriate term be 'information form'.</p>	<p>The length of exposure is related to skin type, so some basic knowledge and use of exposure charts etc is required</p> <p>RHC discussed this issue and decided that it should remain a consent form</p> <p>As above</p> <p>As above</p>
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	<p>6. Additional requirements</p> <p>There are some additional measures which we believe ought to be included in the regulatory elements mentioned in the proposed amendment to the NDRP. These are as follows.</p> <ul style="list-style-type: none"> • It is important that appropriate warning notices are conspicuously displayed at each solarium. As this is an important responsibility of the Responsible Person, this requirement should be included under section 5.4.1. • The Regulatory Impact Statement refers to the licensing of solarium operators. If this is required, section 5.4.1 should impose an additional requirement that the Responsible Person must hold an appropriate authorisation (e.g. a licence) from the relevant regulatory authority. This would also assist in achieving uniformity in the requirements across the jurisdictions. • Neither the Regulatory Impact Statement nor the proposed amendment to the NDRP have any reference to the requirement for Responsible Persons to ensure appropriate maintenance of the equipment and the necessity to ensure constancy of UV output for each sun-tanning unit, particularly in the light of my discussion in item 4, dot point 3 above. This issue must be addressed in the proposed amendment. <p>7. Amendment to Schedule 2 - Categories of Non-Ionizing Radiation</p> <ul style="list-style-type: none"> • This schedule lists the non-ionizing radiation apparatus that requires regulatory control, and it is proposed that 'a solarium used for cosmetic purposes' be such an apparatus. The proposed definition of 'solarium' relates to it being a commercial establishment containing one or more sun-tanning units. It is therefore the sun-tanning units that are producing the non-ionizing radiation, not the solarium. Consequently, the Amendment to Schedule 2 - Categories of Non-Ionizing Radiation should reference 'sun-tanning units used for cosmetic purposes', as this is what should be subject to the regulatory controls, rather than the establishment housing such units. <p>8. Glossary</p>	<p>Agreed and amended</p> <p>Authorisation is covered in part 4 of NDRP</p> <p>Both the National Forum and the RHC agreed that equipment issues would not be considered at this stage.</p> <p>Agreed and amended</p> <p>All skin types now defined</p>
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	<ul style="list-style-type: none"> • The definition of MED - Minimum Erythmal Dose refers to both skin type 1 and skin type 4. While it is noted that skin type 1 is defined in the glossary, skin type 4 is not. Skin type 4 needs to be either defined or removed from the definition of MED - Minimum Erythmal Dose. Additionally, the reference to skin type 1 must also include a reference to the skin typing methodology to be used. • The definition of Supervision needs to be changed to ensure that the exposure time aspect is adequately incorporated in the definition. This could be achieved by changing the existing definition to `...exposure session is terminated in the intended time.'. • The term `cosmetic procedures' needs to be defined to clarify that it does not include reference to therapeutic medical procedures. • The term `commercial establishment' needs to be defined because a medical practitioner's premises may not be considered a commercial establishment but it might still include a sun-tanning unit being operated for cosmetic purposes. <p>For your information, Queensland has recently amended its Radiation Safety Act 1999 to provide the head of power to prohibit commercial solarium operators from allowing persons under 18 to be exposed in sun-tanning units. I expect that this will become effective from March 2009 once the necessary change to the Radiation Safety Regulation 1999 has been made.</p> <p>Please do not hesitate to contact Ms Paula Veevers, A/Assistant Director, on telephone (07) 3406 8014, if you wish to discuss these changes in more detail.</p>	<p>Amended</p> <p>RHC discussed and agreed that definitions of cosmetic procedures and commercial establishment were not required</p> <p>Noted</p>
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