Contaminated Wounds: A Risk Assessment Challenge

Tim Boland, Safety-in-Engineering Centre of Expertise Lead, Sellafield Ltd., Hinton House, Birchwood Park Avenue, Risley, Warrington, WA3 6GR

Richard Cooper, Safety Process and Methodology, Sellafield Ltd., Hinton House, Birchwood Park Avenue, Risley, Warrington, WA3 6GR

Gareth Davies, Safety-in-Engineering Centre of Expertise, Sellafield Ltd., Hinton House, Birchwood Park Avenue, Risley, Warrington, WA3 6GR

An injury at work is always unacceptable; an injury that creates a wound even more so. If the wound is contaminated with foreign matter it compounds the problem; if the contamination source is radioactive then the situation becomes very difficult. Even small quantities of radioactive material entering the body through a relatively minor injury can cause significant harm to an individual. The degree of harm depends on several factors including the nature of the radiation and chemical and biological interactions. The harm from the radioactive material can be much greater than that from the wound itself (Long-term harm to well-being due to health uncertainty and medical intervention can also be considerable.) The nuclear sector describes these hazards as “Contaminated Wounds”.

In other industry sectors the hazards potentially leading to physical injury including wounds are managed through the application of legislation such as The Supply of Machinery (Safety) Regulations 2008. Often the hazard management involves straightforward personal harm risk reduction such as guarding of moving parts, isolation of energy sources personal protective equipment, etc.

The short- and long-term consequences of a Contaminated Wound are such that a simple machinery risk assessment, which is relevant good practice for typical conventional wounds, is not suitable or sufficient; a more rigorous and structured process is needed to identify the potential hazard, determine the consequences and develop management strategies and implementation techniques.

Adopting standard radiological risk assessment methodology would result in overly pessimistic and potentially intolerable conditions. This can ultimately lead to the incorrect balance of overall risk where brownfield high hazard reduction activities are involved.

This has led to Sellafield Ltd. developing a structured approach to assessing Contaminated Wounds and identifying appropriate control measures. Decades of experience of operating nuclear facilities has informed the process developers of what constitutes good practice in handling some of the most hazardous of materials.

Firstly, the hazard management strategy is clearly articulated. Opportunities to eliminate wounds by physical barriers and remote operation are identified. Reduction of the potential for harm is examined by removing sharps or heat sources or minimising “hands-on” operations or by reducing inventory by decontamination. Control measures such as administrative restrictions and personal protective equipment are then identified. And finally, arrangements to mitigate harm via emergency arrangements such as medical intervention are detailed.

Next is to gain an understanding of what residual risk remains. Numerical analysis for Contaminated Wounds is fraught with uncertainty both in frequency due to the inherent flexibility of “hands-on” operations and the variability of biological impact. Therefore only “broad brush” understanding is possible with a general recognition that residual risks may be high, particularly for brownfield activities where opportunities for improvement are constrained.

Lastly, the assessment would explicitly state why further risk reduction would be grossly disproportionate. Again, going beyond what is required under a standard machinery risk assessment. This is by comparison with industry-recognised relevant good practice and by detailing what the drawbacks are of further risk reduction measures (typically the introduction of further hazards).

This paper will describe the above approach with examples.

Although Contaminated Wounds, in this sense, are particular to the nuclear sector it is believed that other sectors may have similar challenges and be interested in our approach.

1. Introduction

Despite extensive use of remote technology there are circumstances in the nuclear industry where operators come in close vicinity of radiological materials. This is only where shielding to reduce dose (external) is unnecessary but there remains the risk of radiological materials entering the body (internal dose). A Contaminated Wound is one such mechanism. The consequences of such an event are difficult to quantify but can be high. Getting the balance right between mitigating Contaminated Wound hazards and other safety aspects such as other hazards and the timely removal of legacy high hazards is challenging. This paper shows the approach Sellafield Ltd. takes to assess these risks.

2. What is a Contaminated Wound?

Significant harm can be caused to an individual if radioactive material enters the body (is absorbed) through a wound. The degree of harm depends on a number of factors, but the harm from the radioactive material can be much greater than that from the wound itself (i.e., physical injury). A ‘wound’ is any means by which the protective layer of the skin is damaged such that radioactive material could enter the bloodstream. Wounds are not limited to cuts but include abrasions and burns.

Contaminated Wounds present the potential for life changing impacts, reduced life expectancy or even prompt fatality. They can also severely affect people's well-being due to stress from uncertainty and any medical intervention. Contaminated Wound hazards are not restricted to alpha emitting material but need to be considered wherever operators may come into contact with radioactive material (although the level of consideration should be proportionate to the hazard potential – i.e., significantly greater for 'alpha' than on 'beta/gamma').

3. Conventional Approach to prevention of wounding

The potential for wounds within industry is usually as a consequence of interacting with machinery. In the UK this is regulated by Supply of Machinery (Safety) Regulations 2008. It requires that a set of Essential Health and Safety Requirements are met. Typically, this is via the application of Designated Standards. Designated Standards are categorised as "C" for particular product types, "B" for common safety issues and "A" for fundamental principles for safety. The relevant "A" standard for applications at Sellafield Ltd. is BS EN ISO 12100 'Safety of machinery. General principles for design. Risk assessment and risk reduction'. It requires risk assessment and risk reduction by, in priority, design, safeguarding / protection and information on use. Sellafield Ltd. uses the qualitative scoring approach of PrEN 1050.

The output is a series of identified hazards with a risk score followed by a series of risk reduction measures with a residual risk score.

There is not a requirement for context of why the machine is needed in the first place; the nature of the hazard is only broadly described and alternative non-selected approaches are not mentioned. For conventional hazards this is regarded as proportionate.

4. Nuclear Safety Approach to identification and safety assessment of Contaminated Wound hazards

Essentially this is a 'nuclearised' version of a conventional risk assessment – identify hazards, assess potential severity of harm, consider safety hierarchy (Eliminate, Reduce, Control, Mitigate) and identify suitable and proportionate controls.

For conventional hazards compliance with legislation may be adequate and there is no requirement for detailed up-front justifications. However, the bar is set higher for nuclear hazards and justification of the adequacy of safety including up-front demonstration that nuclear risks are as low as reasonably practicable (ALARP). This requires significant additional effort, including benchmarking against nuclear relevant good practice (RGP), Design Basis Assessment (DBA) principles and Probabilistic Safety Assessment Criteria – the Nuclear Safety Case is the primary vehicle for this. The Contaminated Wounds risk assessment contains more of the rationale than a conventional risk assessment; it is more akin to a safety case.

For those unfamiliar with the nuclear sector, *Nuclear Safety* is comparable with *Process Safety*. Both deal with high consequence events with very low frequencies and both are concerned with containment and control of hazardous materials. However, there is a lower tolerability of risk for nuclear installations, as explained in Health and Safety Executive's (HSE) "The tolerability of risk from nuclear power stations". This results in lower thresholds for severity of harm and the DBA methodology. DBA is very similar to other risk assessment techniques such as Quantitative Risk Analysis (QRA) but with a strong emphasis on demonstrating defence-in-depth, determinism and conservatism. The Office for Nuclear Regulation (ONR) has guidance on their website with more details.

5. Identification of Contaminated Wound hazards

Thorough and systematic hazard/fault identification techniques, including Hazard and Operability Analysis (HAZOP), are used to identify Contaminated Wound hazards, to inform and influence the design/optioneering processes (enabling Contaminated Wound hazards to be eliminated/reduced by design) and to initiate appropriate safety assessment. Contaminated Wounds can arise during installation, operations or subsequent decommissioning operations, as well as during maintenance operations, so it's important the scope of the studies includes these operations as appropriate. Separate Contaminated Wound focused reviews with appropriate representation (including operational safety advisors, human factors, etc) is often an effective approach.

However, it is noted that, in order to ultimately provide sufficient confidence that all Contaminated Wound hazards have been identified, this must be supplemented by techniques which enable visual examination of plant and equipment, so that hazards which could not be reasonably foreseen at the design stage, but are identifiable by physical examination, may be identified and addressed. Such activities are conducted at the manufacturing and commissioning stages, involving designers and maintainers. On existing facilities plant walk-downs are undertaken. Reliance is also placed on workface risk assessment process. Standard operational radiological controls, plant audits and the awareness of operators and maintainers, to ensure that Contaminated Wound hazards do not develop (e.g., from plant degradation such as corrosion) or are not introduced (e.g., introducing sharp tools).

6. Assessing the consequences of Contaminated Wound hazards

Factors which affect Contaminated Wound hazard consequences

For Contaminated Wounds the way in which harm occurs is an internal dose from activity entering the blood stream through a wound and the mechanism for harm is the means by which the skin is broken coincident with the presence of the radioactive material. Wounds provide a mechanism for significant internal dose intake. The activity could be transferred into the blood stream giving rise to a very large dose from very small quantities of radioactive material. The dose received from

a Contaminated Wound will depend on a number of factors and these factors affect how much and how quickly activity is taken into the blood stream and carried to vulnerable organs:

The amount of radioactive material present at the wounding site and it's mobility

Clearly the higher the levels of contamination present at the site of the wounding, the higher the likely uptake of radioactive material by any wound sustained. Similarly, the more mobile it is, the easier it is to pass from the contaminated surface to the wound.

The depth and location of the wound

The dose will be affected by whether the wound is in the subcutaneous layer of the skin or into the muscle layer. The type and position of the wound will affect the ease with which activity will enter blood stream. The absorption of a soluble radionuclide into the bloodstream would typically follow the following order (greatest to lowest harm potential):

1) Intravenous injection

2) Puncture/laceration/abrasion

3) Burned skin

4) Intact skin

The isotopic composition of the radioactive material

The potential for significant consequences from Contaminated Wounds arises where the inventory contains a high proportion of transuranic nuclides, of which the most onerous is plutonium with americium and curium also being significant. Uranium is a lesser hazard, with greater quantities being required to give a significant dose, so that it is unlikely such quantities could be readily transferred into the blood stream.

The dose from an alpha Contaminated Wound is normally much higher than from a beta Contaminated Wound. Dose coefficients for plutonium isotopes are approximately four orders of magnitude greater than those for common beta emitters. Very small quantities of plutonium or other actinides entering the bloodstream, if untreated, could potentially result in a committed effective dose (a measure of the cumulative dose over time (50 years) from the presence of the material in the body, taking into account weighting factors) of several Sieverts (Sv).

For beta emitters, their penetrative power means skin dose (i.e. external to the person) is likely to be the dominant hazard, rather than absorption (internal dose).

Nature and solubility of the material

Material in a wound may be classed in accordance with its chemical and physical form which will influence the anticipated behaviour. Soluble materials may be described by their retention at the wound site (weak, moderate, strong, and avid). Insoluble materials are classed as colloid, particle, and fragment. The dose coefficients for the different forms are of similar order (with the exception of a fragment which is typically an order of magnitude less). The difference is not significant in terms of obtaining an approximate idea of the potential consequence. However, the solubility is significant in determining the rate at which the activity will enter the blood stream (and thus the time available to optimise the success of medical intervention).

Estimating the unmitigated consequences of a Contaminated Wound

Due to the complexity of the different factors affecting the dose incurred, described above, it is not considered meaningful to make a precise, numerical estimate of the potential unmitigated dose from a Contaminated Wound to support Nuclear Safety Assessment. To give an indication of the problem, the Sellafield Ltd. operational safety community believe that, due to uncertainties in determining the precise nature of a particular wounding event, any such estimates could have an error bar of up to four orders of magnitude. This can lead to excessive conservatism and the wrong balance of risk.

A more qualitative understanding of the significance of the hazard needs to be developed, to influence decision-making. This is typically informed by operational experience of events.

Where beta/gamma material or certain nuclides (e.g., uranium) are concerned, a relatively low unmitigated consequences may be justified.

For material containing Plutonium or other transuranic nuclides with high specific activities (and committed effective dose coefficients), unless consultation with the operational safety advisor allows justification otherwise, it will be assumed that the unmitigated worker consequences could be very high (>1000mSv). However, where this is done, it is highlighted in the safety documentation that this is a conservative assumption for DBA assessment purposes and is subject to significant uncertainty. For risk assessment, a 20-1000mSv dose would be considered more appropriate - doing otherwise (i.e., assessing risk based on worker consequences >1000mSv) would be considered to be more akin to a worst case than a best estimate, and would therefore be likely to overestimate the contribution to overall plant risk from Contaminated Wounds hazards. (Where there is uncertainty recommended practice is usually to conduct sensitivity assessments, in practice this achieved by exploring what further measures could or could not be implemented as explained below in section 10.)

Isotopic blend	Material /Mechanism	Potential for mitigation	Notes
Pu or other actinides	Soluble material (typically Pu nitrate) in wound	High/Moderate	The hazard potential of plutonium (americium and curium) material will be dependent on its physical and chemical form and the mechanism of transfer into the bloodstream. Scenarios with the potential for intravenous injection (e.g., sample needles) give the most direct route and potentially highest consequence. Material from wound site may transfer relatively quickly into the blood stream, dependent on form. Intervention with a chelate compound may be successful but carries risk of other effects.
	Insoluble material (typically Pu oxide)	High	Material is likely to remain at wound site and take time to reach blood stream. Surgical intervention is likely to be successful in reducing dose but may have other undesirable ramifications.
Medium Active (MA) waste (beta, gamma and some alpha)	All mechanisms	High	MA streams may contain more than trace quantities of plutonium or other transuranic nuclides, however, there will be a significant proportion of beta / gamma-emitting nuclides present. The potential consequences of a Contaminated Wound will depend on the relative isotopic composition and may be significant. It would not normally be expected that sufficient material could be present to result in a very high dose, because of the need to protect against radiation, however, scenarios should be considered case by case. Intravenous injection may pose the most significant hazard.
Uranium (235,238)	Solid/Insoluble	High	The dose coefficients expressed as Sv/Bq are orders of magnitude lower for uranium than plutonium. The specific activity (Bq/g) of the common uranium isotopes (235,238) is several orders of magnitude lower such that much greater quantities are required to give a significant dose. Several grams would need to be absorbed into the bloodstream to exceed 1Sv which is extremely unlikely when considering transfer factors.
	Soluble	Low	Uranium Contaminated Wounds should not be treated with a chelating agent injection as uranium is chemo-toxic to the kidneys and a chelating agent would increase the uranium concentration in the kidneys
High Active (HA) waste	All	High (or may be unnecessary)	HA material contains sufficient gamma emitters that prohibit manual operations due to the external whole-body gamma radiation dose rate.
Low Active (LA) waste	All	High (or may be unnecessary)	LA streams typically do not contain more than trace quantities of plutonium or other transuranic nuclides; hence the potential consequences of a Contaminated Wound are likely to be minor

Table 1 provides information relating to the varying levels of severity of Contaminated Wounds for different materials.

7. Developing Hazard Management Strategies for Contaminated Wound hazards

Development of the approach to Hazard Management for Contaminated Wounds at the Design Stage

When developing hazard management strategies, it is useful to think of a hazard in terms of three aspects - the **hazardous material**, the nature of the **harm** it presents and the **mechanism** by which harm occurs. For Contaminated Wounds the way in which harm occurs is an internal dose from activity entering the blood stream through a wound via absorption and the mechanism for harm is the means by which the skin is broken coincident with the presence of the radioactive material/contamination.

The approaches available for hazard management can be considered to fall into one of four categories forming a hierarchy - Eliminate, Reduce, Control or Mitigate (referred to at Sellafield Ltd. as the 'Hazard Management Hierarchy'. Figure 1 below illustrates how this relates to a Contaminated Wound hazard:

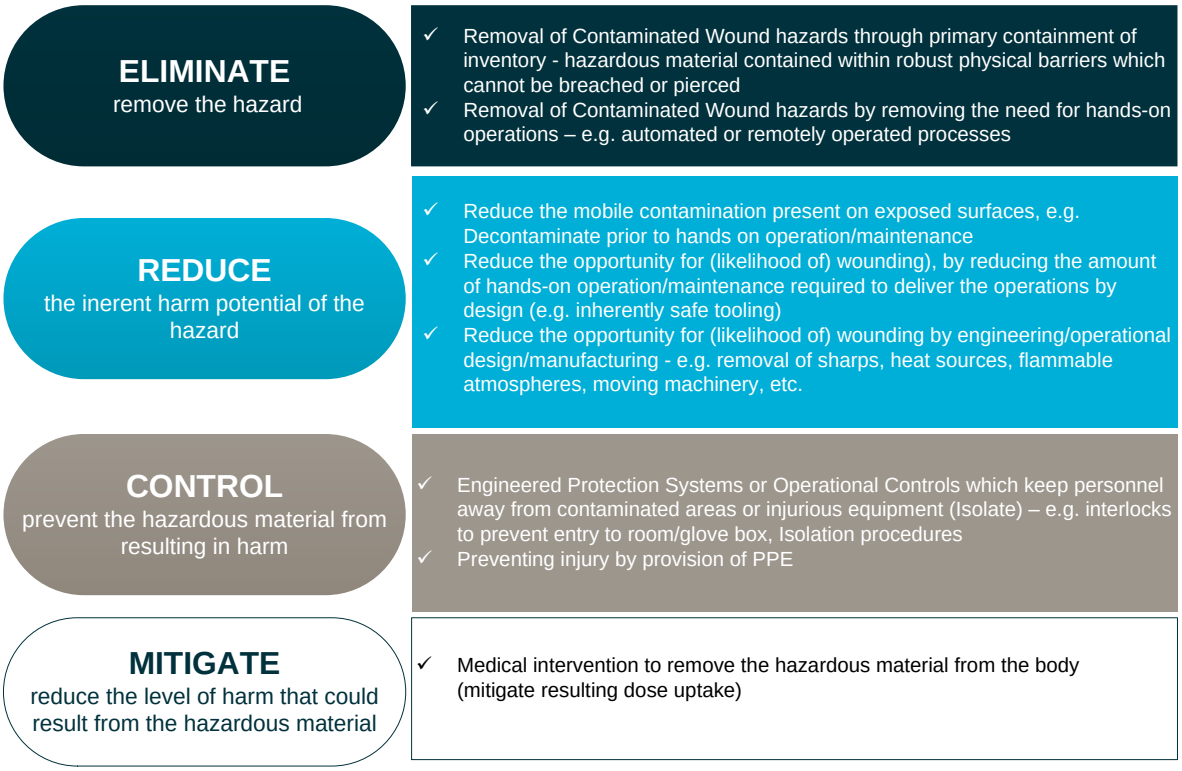

Figure 1 – Contaminated Wound Hazard Management

This is an iterative process requiring multi-disciplined collaboration and the balancing of risks from different nuclear and non-nuclear hazards, as well as numerous other factors, to arrive at a design that has struck an appropriate risk balance and can therefore be demonstrated to reduce risks ALARP.

However, given the potential consequence and risk associated with Contaminated Wounds, the requirement to manage the wounding hazard can impact significantly on the direction of a project/modification, e.g., away from an initially envisaged manual/hands-on approach, to one that is remote or semi-remote. Hence, it is essential that Contaminated Wound hazards be identified early on in a project/task, and their significance conveyed to all those involved in influencing the safe design and operation of the facility, in order to guide option selection and design development.

(Option selection within Sellafield Ltd. is complicated by the business drivers typically being hazard reduction. Our investments are to reduce existing high hazards (i.e. decommissioning of legacy facilities and management of waste). Time to delivery can be a safety consideration in and of itself. We acknowledge that we may incur increased risk over the short-term for long-term risk reduction. Sellafield Ltd. like any business must consider various sometimes conflicting factors. The Nuclear Decommissioning Authority value framework is used to help guide decision-making process. Values considered are: Health and Safety; Security; Environment; Risk/Hazard Reduction; Socio-economic impacts; Lifetime cost; Enabling the Mission.)

The best opportunity to reduce the risk of Contaminated Wounds is early in the design of the project/modification. The aim is to drive the design as high up the above Hazard Management hierarchy as possible (i.e. Eliminate/Reduce Contaminated Wound hazards as far as practicable, then develop Controls to manage the remaining risk). Again, a separate Contaminated

Wound focused review with appropriate representation (including operational safety advisors, human factors, etc) can be an effective approach.

In order to support an overall 'ALARP justification', the key decisions relating to the management of Contaminated Wounds are clearly documented and justified.

Mitigation of the harm (consequences) associated with Contaminated Wounds

Interventions can significantly reduce the dose incurred after the wound is sustained by removing activity from the body via:

- **Surgical intervention** – this involves removal of the tissue around the wound. The intent is to remove activity before a significant proportion can enter the bloodstream and be transported to vulnerable organs. It is most effective if undertaken within a few hours of the event. The selection of the level of intervention will be based on an initial assessment of the potential dose from a wound.
- **Use of Chelating Agents** - These agents bind to heavy metals in the body so that they are prevented from binding to organs. The activity is bound to the chelating agent and excreted from the body. The effectiveness of chelating agent is dependent on the chemical form of the material and the timing of the treatment. It is most effective for soluble forms such as nitrates and ineffective for less soluble forms such as oxides.

Timely intervention is known to be extremely effective in reducing the dose ultimately received by individuals. Several Contaminated Wound events have occurred on the Sellafield site during its decades of operation. The majority of events ultimately resulted in low dose uptake, of a few mSv or less. Two events have resulted in a dose uptake exceeding the annual Sellafield site dose limit.

A review of the effectiveness of decontamination procedures by wound excision considered the 6 cases which occurred between 1996 and 2019. In all cases, the procedures were able to reduce wound contamination to low levels. In the 1996 incident, it was estimated that 98% of the activity was excised. In 3 other cases >99% was removed. In two cases, up to a third of the activity remained. These were relatively low severity incidents, so this may have been as a result of a balanced decision-making process based on the diminishing benefit of further activity reduction against an invasive excision procedure.

However, such intervention is low down in the Safety Hierarchy and has significant lifetime implications for the individual, so other hazard management approaches higher up the hierarchy are developed, as far as is reasonably practicable. Each wounding event is different, resulting in different combinations of the factors affecting dose, described above. It is not feasible or desirable to try to predict with any accuracy the level of consequence mitigation that will be delivered in any particular event.

However, the above evidence provides significant confidence that intervention procedures at Sellafield Ltd. provide a robust mitigating barrier against incurring high doses from a Contaminated Wound and appropriate credit is taken for this when presenting the defence in depth arguments, as discussed further below.

8. Demonstrate that there is sufficient protection (defence in depth) against any challenges to the identified hazard management strategies.

The risk assessment needs to convey a clear understanding of the hazard, the risk posed and the means of controlling the hazard. The methods for control of Contaminated Wounds are likely to encompass a range of aspects (generic standards/operational controls, facility-specific design provision, facility specific controls). The balance of these will vary depending on the facility and stage of life cycle. A key concern for Sellafield Ltd., if not nationally, is the timely reduction in hazard from legacy radiological materials that have accumulated from previous operations.

A Contaminated Wounds risk assessment during the design phases of a project/task will be necessarily different to an operational risk assessment. Effectively the risk assessment evolves. In the design phase there should be a significant focus on demonstrating that all reasonably practicable measures have been taken to Eliminate or Reduce Contaminated Wound risk, adopting approaches outlined in Figure 1. Control/Mitigation of Contaminated Wounds, whilst limited as outlined in Figure 1, can then be framed against this backdrop.

On existing facilities, the scope for Eliminating/Reducing Contaminated Wound hazards is much more limited – many of these design decisions will have already been taken ('banked') and re-design will not be a realistic proposition. The principles around hazard management outlined above still need to be explicitly considered and justified (e.g., consideration of the hazard management and safety hierarchies). However, the focus will necessarily be on Control & Mitigation and it is likely that significant reliance will need to be placed on measures lower down in the safety hierarchy, i.e., operational controls and mitigation via intervention, as discussed above.

Approach to Safety Assessment of Contaminated Wounds Hazards

Application of a DBA Scheme is generally accepted as nuclear industry RGP approach to assessing and demonstrating the adequacy of defence in depth against nuclear hazards – this is the approach advocated within the ONR Guidance

However, such an approach is problematic for Contaminated Wound hazards. Application of a DBA scheme requires:

1. Estimation of unmitigated consequences
2. Identification and definition of specific initiating events

3. Estimation of associated Initiating Event Frequencies (IEF)
4. Determination of the DBA region (Design Basis Region 1 [DB1] or Region [DB2], the number of basket safety measures required)
5. Identification of discrete safety measures, each independently preventing progression of each initiating event or sufficiently mitigating the resulting consequences

Due to the nature and complexity of Contaminated Wound hazards, meaningful assessment/quantification of these aspects is not considered practicable, and on that basis, application of a formal DBA scheme is not adopted for Contaminated Wound hazards. A more qualitative approach is required.

As previously suggested, unless operational experience allows justification otherwise, it is conservatively assumed that the unmitigated consequences could be very high (>1000mSv). In principle, this would place the hazards in the DB2 region requiring at least two robust (high confidence) independent barriers to prevent delivery of the unmitigated consequences. From experience, for Contaminated Wound hazards, it is difficult to demonstrate this level of defence in depth against all potential scenarios.

For some scenarios it may be practicable to provide engineered protection, or a combination of engineered protection and operational controls (e.g., interlocks/controls preventing access of hands when a potentially hazardous operation is undertaken). However, it's important to be clear that this doesn't prevent all Contaminated Wounds, only those associated with that particular piece of machinery. For many scenarios, fully independent preventative engineered protection may not be possible or not deemed reasonably practicable (such judgements on practicability are heavily influenced by the risk context of the operations), and reliance needs to be placed on a combination of other (primarily operational) measures with differing associated levels of confidence.

In such situations, where there is a perceived 'shortfall against RGP', there is a much greater onus on robustly demonstrating that all reasonably practicable actions/measures have been taken to reduce the associated Contaminated Wound risk. This then becomes the primary aim of a Contaminated Wound risk assessment.

In terms of risk assessment approach, experience shows that a barrier analysis-type approach (similar to bow tie diagrams) can be effective in such situations, enabling a clear demonstration of the level and robustness of the defence in depth provided and a robust demonstration that risks are ALARP.

As detailed in Figure 1, the approaches to Contaminated Wound hazard management fall in the following categories

- Eliminate Contaminated Wound risk through primary containment of inventory
- Eliminate Contaminated Wound risk by removing the need for hands-on operations
- Reduce the mobile contamination on exposed surfaces
- Reduce the opportunity for (likelihood of) wounding), by reducing the amount of hands-on operation/maintenance required to deliver the operations
- Reduce the opportunity for (likelihood of) wounding by engineering design or operational controls
- Control the Contaminated Wound hazard through provision of engineered protection systems which prevent wounding
- Operational controls which aim to prevent wounding)
- Mitigation of Contaminated Wound consequences (dose) through medical intervention

A Contaminated Wound risk assessment needs to clearly describe and underpin what has been done/will be done in the above categories and make a reasoned argument as to why this is judged to be adequate. These different aspects of hazard management are not strictly 'barriers', but they all contribute (to various extents) to managing the Contaminated Wound risk. A tabular presentation can be an effective way of presenting this information. However, other styles of presentation may be equally valid.

Given the variety of the different approaches adopted, a Claims/Arguments/Evidence mindset is particularly important here – What are we claiming about the particular measure (how does it contribute to Contaminated Wound risk reduction and to what extent?), how will it be implemented and (where relevant) how are we confident it will continue to be implemented over the lifecycle of the operations? How is/will this be evidenced? Appendix A provides an indication of the type of evidence that might be cited.

It is important to acknowledge the dependencies between the different measures adopted –a question set can be useful in articulating these.

A healthy safety culture on Contaminated Wounds is essential. Without this the measures described are unlikely to be robustly implemented. Therefore, the risk assessment will comment on how such a safety culture is nurtured on the facility.

Judging overall adequacy of defence in depth

Where unmitigated worker consequences <20mSv can be underpinned, it is argued that the level of defence in depth is adequate and proportionate, taking credit for standard radiological protection arrangements.

In the context of broad DBA comparison, for a barrier (or combination of measures) to be claimed as equivalent to a DBA basket safety measure, they would be expected to prevent fault progression or substantially mitigate the potential consequences of the Contaminated Wound hazard, and it should be clear in the risk assessment how it does so (e.g., by demonstrating with high confidence that it would prevent fault initiation in the first place, or otherwise terminate the fault once initiated).

Where high unmitigated consequences, 20-1000mSv are credible it is necessary to recognise that the safety provision falls short of industry RGP (i.e., a 'DB2-level of provision') – this could be true from a number of perspectives - the associated analysis of the barriers outlined above will have drawn out these 'deficiencies', potentially including:

- Inability to identify two high confidence fully independent protective measures that can be demonstrated to prevent a Contaminated Wound in all scenarios
- Reliance on multiple partial barriers, that provide a degree of protection which is difficult to quantify
- Reliance on measures/barriers that are low down safety hierarchy (operational)
- Reliance on medical intervention which, whilst robust, its effectiveness cannot be guaranteed

In this situation, adequacy can only really be demonstrated by showing that all reasonably practicable measures to reduce Contaminated Wound risk have been incorporated – this is discussed further in Section 9 below.

9. Identify limits and conditions in the interest of nuclear safety (Safe Operating Envelope).

Nuclear facilities are required by the Nuclear Site License to identify key limits and conditions in the interest of safety and ensure they remain in full working order. This is typically achieved through a process of 'Safety Designation', where important operational controls and engineered systems which deliver important safety functions are categorised and classified. The category/classification dictates other processes relating to underpinning and Examination, Inspection Maintenance and Testing (EIMT) requirements. Safety Designation therefore:

i. Highlights the level of importance to nuclear safety of the equipment/operational control, thereby enabling safe operation of the facility

ii. Triggers tiered engineering/human factors substantiation processes which demonstrate that the equipment/operational control will deliver the associated safety function to an appropriate degree of confidence

iii. Triggers the development of suitable outage arrangements for equipment

iv. Enables demonstrable compliance with the associated limit or condition (and enables ONR auditing of these)

v. Provides clarity to operators/maintainers as to what is important to nuclear safety – informs training, decision making and enables prioritisation

vi. Triggers processes which ensure that confidence in the delivery of key safety functions is ensured over the lifecycle of the design/operations – e.g., EIMT, auditing

vii. Ensures equipment/controls are highlighted as important within operating and maintenance instructions

This applies to Contaminated Wounds hazards the same as to other nuclear hazards. If a particular piece of equipment or control plays a role in reducing the Contaminated Wounds risk, then it is a potential candidate for Safety Designation, depending on its contribution to nuclear safety. When determining the type and level of Safety Designation, it is necessary to understand the 'safety function' of the equipment or operation with respect to Contaminated Wounds i.e., what is it really doing for us and in what circumstances? How important to nuclear safety is it within the overall context of the operations? The peculiarities of a Contaminated Wounds risk assessment are such that this is not straightforward and can require a significant level of judgement.

10. Demonstrate understanding of, and articulate, the nuclear residual risk associated with the hazards and demonstrate that risks from nuclear hazards are managed to be ALARP

Articulation of the residual nuclear risk associated with Contaminated Wounds

The standard nuclear industry approach for assessing nuclear hazards is to quantify the risk associated with various fault conditions and compare this with Probabilistic Risk Criteria, which are effectively set by the ONR.

However, for Contaminated Wound scenarios, attempts to numerically quantify the risk for comparison against risk criteria will be ineffectual. Qualitative judgements on the likely consequence will give an indication of the dose band in which the consequence could fall but the complexity of factors influencing both consequence and frequency is such that precise numerical estimation of the risk is often not a beneficial aid to understanding.

An understanding of the risk and the factors which govern that risk is essential to the demonstration that the risks have been reduced ALARP. However, a precise numerical value is not essential to influence the level of effort expended in demonstration of ALARP.

For facilities where the risk of significant consequence is already very low because of the nature of the material, or where the design provision has truly eliminated the potential for wounding then, subject to appropriate underpinning of this claim, it may be concluded that the Contaminated Wound risk will be very low and potentially fall in the broadly acceptable region.

However, facilities where this is not the case (e.g., most existing facilities that manage alpha emitting materials), it is accepted that the residual risk is high (in the tolerable region) and arguments focus on the demonstration that the residual risk is ALARP, in line with the guidance in the following section. It is theoretically possible to have a situation where the risk is judged to be intolerable but ALARP. However, it is difficult, in practice, based upon experience, to conceive of such a situation at Sellafield, as long as existing site arrangements have been applied and RGP has been robustly considered (see discussion in the following section).

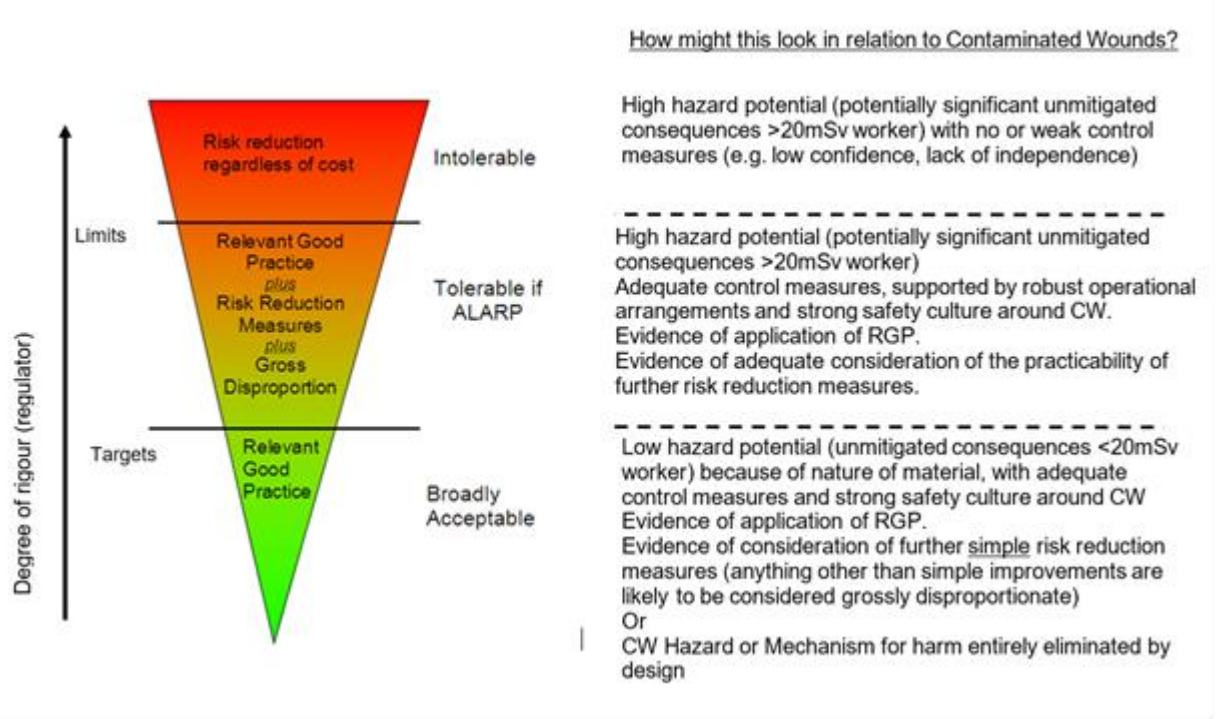

Figure 2 – “Risk Carrot” for Contaminated Wounds (CW)

Demonstration that risks have been reduced ALARP

Key decisions made during design development must be justified, taking cognisance of the need to balance the risks of different, potentially competing, hazards. Where the potential for high unmitigated doses from Contaminated Wounds exists, the justification must explicitly address the reasons why it is/was not reasonably practicable to eliminate the hazard within the context of the project’s drivers, e.g. legacy high hazard reduction.

Demonstration that the operations align with RGP is central to any demonstration that risks are ALARP. Sellafield Ltd. has a wealth of experience from facilities that manage alpha emitting materials and has developed nuclear industry good practice (considered to represent nuclear industry RGP), much of which is incorporated in design standards and guidance. There is a Sellafield Ltd. glovebox forum which enables sharing of Learning From Experience (LFE) and good practice and links with other nuclear operators through the National Nuclear Glove Box Forum. The UK Alpha Resilience and Capability programme is focused on establishing and capturing RGP relating to alpha operations. If appropriate Sellafield Ltd. design and operational standards have been applied and LFE sought and considered, then it can reasonably be asserted that the design and operations are in line with RGP.

Given the likely high (tolerable) residual risk associated with Contaminated Wounds, as discussed above, and the likelihood that the level of defence in depth is unlikely to fully align with expectations of an industry DBA assessment for all scenarios, ‘ALARP arguments’ will need to clearly explain what further improvements to reduce the associated residual risk have been considered, and why the detriment associated with these is judged to be grossly disproportionate to the risk reduction that would be achieved. These arguments need to be robustly underpinned.

This can be achieved by considering the different categories of hazard management approaches in Figure 1. Is there anything more we could do? i.e.:

- Further reduce the amount of hands-on operation/maintenance required to deliver the operations?

- Further reduce the opportunity for wounding by modifying the engineering design or operational controls?
- Further reduce the potential contamination levels on exposed surfaces?
- Further reduce the potential for degraded plant conditions, such as could generate injury risks?
- Incorporate or improve further engineered barriers which prevent the hazard (prevent wounding)?
- Incorporate or improve further operational barriers which prevent the hazard (prevent wounding)?

This is another area where a separate, Contaminated Wound focused, review with appropriate representation can be an effective approach. The risk assessment should explain what has been considered and why the detriment of implementing it is judged to be grossly disproportionate to the risk benefit that would be achieved (this means some qualitative assessment of the potential risk benefit is necessary). Justifications could include:

- The risk benefit achieved would be minimal due to human dependencies - this argument would require support from human factors)
- Implementation would incur unacceptable design and lifetime cost, time and trouble - this argument would require support from engineering design & operations

11. Examples

Because of the sensitivity of the topic, it is not appropriate to give real examples of assessments that Sellafield Ltd. have made. Instead, this section gives examples of the barriers considered in an assessment. Each barrier would be considered in turn with context and underpinning relevant to the particular facility. Where a barrier is not appropriate, or only partial, the reasons would be given.

Measures to Eliminate or Reduce

- Primary containment eliminates Contaminated Wound risk from bulk inventory
- Optioneering and Design decisions to avoid hands-on operations/maintenance wherever practicable
- Design tools/engineered systems provided to reduce need for hands-on contact
- Sharp edges, heat sources, stored energy sources, flammable substances, aggressive chemicals, glassware, etc, such as could cause injury, avoided in the engineering design
- Guarding associated with moving machinery
- Need for sharp or otherwise injurious tooling minimised by design
- Human factors design input and ergonomic design to minimise potential for injury
- Defects identified during manufacture, installation and commissioning are addressed and contaminated hazards removed or suitably protected
- Sharps audits and walkdowns on a defined basis providing further opportunities to identify and minimise injury risks
- Procedures to ensure adequate control of operations to minimise exposure to or introduction of sharps
- Activity containment measures that minimise contamination levels on exposed surfaces (e.g., ventilation systems)
- Contamination control (Housekeeping) to prevent build-up of contamination levels on exposed surfaces
- Monitoring and decontaminating items prior to handling to reduce contamination on exposed surfaces
- Assets are appropriately maintained and inspected to safeguard against hazards introduce by wear/degradation

Measures to Control

- Engineered interlocks that prevent hands on operations and maintenance in the vicinity of injurious machinery
- Electrical isolations that prevent hands on maintenance in the vicinity of injurious machinery
- Appropriate personal protective equipment

Measures to Mitigate

- Medical intervention arrangements

12. Summary

Contaminated Wounds are challenging hazards for risk assessment. There is considerable uncertainty in the theoretical estimation of consequences and the effectiveness of mitigation. This can lead to excessive conservatism with a detriment to the Sellafield Ltd. mission of reducing legacy hazards sooner. A structured approach is required that goes beyond conventional machinery risk assessment and incorporates safety case methods of articulating an argument.

Sellafield Ltd. identifies potential Contaminated Wound hazards; qualitatively assesses consequences; presents a strategy for their management and from that identifies equipment and operations vital to that strategy. Finally, all further measures are explored and where not adopted the reasons given. The table below summarises:

Demonstrate that all Contaminated Wound hazards within the scope of the risk assessment have been identified (as far as reasonably practicable)	• Clearly describe the Scope of the operations – this should include any associated maintenance operations which present Contaminated Wound risk. Preparatory works may also be a consideration. • Explain what hazard/fault identification has been undertaken and provide confidence in its robustness and completeness in relation to Contaminated Wound. Note that hazard/fault identification processes used during the design phase can only go so far - the plant-based risk assessment processes also have a key role in identification and removal/protection against potential introduced/emergent Contaminated Wound hazards • Clearly describe/summarise the identified scenarios in which a Contaminated Wound could be received during the operations
Demonstrate that the significance of the Contaminated Wound hazard is understood	• Describe the nature of the contaminated material and its inherent hazard potential with respect to Contaminated Wound • Consider in consultation with operational safety advisor whether it may be possible to justify that unmitigated consequences from the Contaminated Wound hazards are <20mSv • If not, conservatively assume unmitigated consequences from the Contaminated Wound hazards >1000mSv for DBA purposes (conservative) and >20mSv for risk assessment (Best Estimate)
Demonstrate how Contaminated Wound hazards are being managed (nuclear hazard management)	• Explain why it has not been possible to eliminate the Contaminated Wound hazard - describe and justify optioneering decisions with respect to Contaminated Wounds – provide confidence that Contaminated Wounds have been appropriately and proportionately considered during development of the design/modification • Provide confidence that the proposed design and operations are in line with RGP - If appropriate Sellafield Ltd. design and operational standards have been applied and LFE sought and considered, then it can reasonably be asserted that this is the case • Detail all the actions taken/measures employed to Eliminate, Reduce, Control and Mitigate the Contaminated Wound hazard considering the different categories of hazard management approaches in Figure 1 – Adopt a Claims/Arguments/Evidence mindset and consider using a barrier analysis-type approach. • Recognise and describe the dependencies between the different measures adopted. • Provide confidence that there is a healthy safety culture on the facility with respect to control of Contaminated Wounds, recognising that that this is crucial • Draw a conclusion about the overall adequacy of the defence in depth provided against Contaminated Wounds – where high unmitigated consequences can result, it is likely that we
Demonstrate that there is sufficient protection (defence in depth) against any challenges to the identified hazard management strategies, proportionate to the significance of the Contaminated Wound hazards.	

	will have to recognise qualitatively that the level of defence in depth falls short of what might be expected if nuclear industry DBA criteria were applied, prompting the need for detailed 'ALARP considerations'
Identify limits and conditions in the interest of nuclear safety (Safe Operating Envelope)	• Identify the Safe Operating Envelope including appropriate limits and conditions – consider advice in Section 9 • Consider use of stakeholder group to consider and agree (and justify) an appropriate set of limits and conditions/safety designations for the facility, related to Contaminated Wounds
Demonstrate understanding of, and articulate, the nuclear risk associated with the Contaminated Wound hazards and demonstrate that risks from them are managed to be ALARP, within the broader risk context of the facility.	• Make a qualitative assessment of the level of residual risk presented by Contaminated Wounds, considering the advice in Section 10 • Consider the different categories of hazard management approaches in Figure 1. Is there anything more we could do? • Explain what improvements have been considered and, where potential improvements have rejected, explain why the detriment of implementing them is judged to be grossly disproportionate to the risk benefit that would be achieved. Such arguments should recognise the overall risk context of the mission and the need to balance the risks from multiple hazards and other project requirements

Table 2 – Summary of a Contaminated Wounds Paper

Sellafield Ltd. believes this approach ensures that Contaminated Wounds are fully considered and are managed reducing risks so far as reasonably practicable.

Although this paper is about a hazard particular to the nuclear sector other industries may have similar hazards that may benefit from a similar approach.

References

Supply of Machinery (Safety) Regulations 2008, UK Statutory Instrument 1597.

BS EN ISO 12100: 2010 'Safety of machinery. General principles for design. Risk assessment and risk reduction'. British Standards Institute 2010.

BS EN 1050: 1997 'Safety of machinery. Principles for risk assessment' (withdrawn). British Standards Institute 1997.

HSE, 'The tolerability of risk from nuclear power stations', HMSO 1992.

ONR, 'Design Basis Analysis', NS-TAST-GD-006 Rev 5, October 2020.